State of California Department of Consumer Affairs

Memorandum

To: Board Members Date: April 20, 2006

From: Jan E. Perez
Legislation and Regulation Coordinator

Subject: Prescription Drop Boxes and Automated Self-Use Delivery Devices For Refill Prescriptions: Amendment to repeal 16 CCR § 1717(e) and to add 16 CCR 16, §1713

At this meeting the board is conducting a regulation hearing to establish requirements for prescription drop boxes and automated self-use delivery devices for refill prescriptions; proposed amendment to repeal 16 CCR §1717(e) and to add 16 CCR §1713. The 45-day notice for the regulation hearing was published on February 24, 2006. A copy of the original language is in Attachment A.

The board received seven written comments on the proposed regulation. Upon review of the comments received, staff revised the proposed language to incorporate some of the recommended changes as well as those discussed at the April 19 Legislation and Regulation Committee meeting. The changes are technical in nature and will further clarify the meaning of "refill" prescription and the location of the device. A copy of the April 19, 2006 revised language is in Attachment B. Additions to the regulation are marked in double underline and deletions are marked in double strikeout.

Additional testimony will be taken during the hearing at the board meeting. Upon conclusion of the regulation hearing, the board will discuss the proposed regulation and determine what action you wish to take.

The Legislation and Regulation Committee recommends that the board adopt the revised regulation language dated April 19, 2006. Alternatively, the board may consider the revised draft with additional modifications as suggested during the regulation hearing.

Any changes to the original regulation will require at least a 15-day notice. One thing to keep in mind when discussing whether or not to revise the regulation is, that the board has used similar language in the regulation to approve the waivers for the use of automated delivery devices. While the board has received comments on the regulation, there has been no demonstrated need, based on the actual use of the machines, to change the regulation.

Attachment C contains copies of the written comments received by the board. Attachment D is the board's response to written comments.

Attachment A

Original Language

Board of Pharmacy
Specific Language

Adopt Section 1713 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1713. Receipt and Delivery of Prescriptions and Prescription Medications.

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.

(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.

(d) A pharmacy may use an automated delivery device to deliver refilled prescription medications provided:

(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.

(2) A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription mediation to that patient.

(3) The device has a means to identify each patient and only release that patient's prescription medications.

(4) The pharmacy does not use the device to deliver refill prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).

(5) The pharmacy provides a means for each patient to obtain an immediate telephone or in-person consultation with a pharmacist if requested by the patient.

(6) The device is located adjacent to the licensed pharmacy counter.

(7) The device is secure from access and removal by unauthorized individuals.

(8) The pharmacy is responsible for the prescription medications stored in the device.

(9) Any incident involving the device where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

(10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).

(e) Any pharmacy making use of an automated delivery device as permitted by subdivision (d) shall maintain, and on an annual basis review, written policies and procedures providing for:

(1) Maintaining the security of the automated delivery device and the dangerous drugs within the device.

(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed.

(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the automated delivery device.

(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filling procedures for the automated delivery device.

(5) Orienting participating patients on use of the automated delivery device, notifying patients when expected prescription medications are not available in the device, and ensuring that patient use of the device does not interfere with delivery of prescription medications.

(6)Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions.

(f) Written policies and procedures shall be maintained at least three years beyond the last use of an automated delivery device.

Note: Authority cited: Sections 4005, 4075, and 4114 Business and Professions Code. Reference: Sections 4005, 4052, 4116 and 4117 Business and Professions Code.

Amend Section 1717 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1717. ~~Pharmaceutical~~ Pharmacy Practice.

~~(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.~~
Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:

(1) a patient med pak is reused only for the same patient;
(2) no more than a one-month supply is dispensed at one time; and
(3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."

(b) In addition to the requirements of Business and Professions Code Section 4040, the following information shall be maintained for each prescription on file and shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist ~~preceptor~~ before they are dispensed.
(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and
(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.
(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing.
Chart orders as defined in Section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.

(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005.

(e) ~~No licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.~~
~~However, a licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. The Board may in its sole discretion waive this application of the regulation for good cause shown.~~

~~(f)~~ A pharmacist may transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, 1306.26.
Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of Section 1716. Information maintained by each pharmacy shall at least include:
(1) Identification of pharmacist(s) transferring information;
(2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;
(3) Original date and last dispensing date;
(4) Number of refills and date originally authorized;
(5) Number of refills remaining but not dispensed;
(6) Number of refills transferred.

~~(g)~~ (f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

Note: Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116, 4117 and 4342, Business and Professions Code.

Attachment B

Revised Language
April 19, 2006

Board of Pharmacy
Specific Language

April 19, 2006

Adopt Section 1713 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1713. Receipt and Delivery of Prescriptions and Prescription Medications.

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.
(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.
(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.
(d) A pharmacy may use an automated delivery device to deliver previously dispensed ~~refilled~~ prescription medications provided:

(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.
(2) A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription medication ~~mediation~~ to that patient.
(3) The device has a means to identify each patient and only release that patient's prescription medications.
(4) The pharmacy does not use the device to deliver previously dispensed ~~refill~~ prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).
(5) The pharmacy provides a means for each patient to request and obtain an immediate consultation with a pharmacist, either in-person or via telephone. ~~The pharmacy provides a means for each patient to obtain an immediate telephone or in-person consultation with a pharmacist if requested by the patient.~~
(6) The device is located adjacent to the secure pharmacy area~~licensed pharmacy counter~~.
(7) The device is secure from access and removal by unauthorized individuals.
(8) The pharmacy is responsible for the prescription medications stored in the device.
(9) Any incident involving the device where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.
(10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).

(e) Any pharmacy making use of an automated delivery device as permitted by subdivision (d) shall maintain, and on an annual basis review, written policies and procedures providing for:

(1) Maintaining the security of the automated delivery device and the dangerous drugs within the device.

(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed.

(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the automated delivery device.

(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filling procedures for the automated delivery device.

(5) Orienting participating patients on use of the automated delivery device, notifying patients when expected prescription medications are not available in the device, and ensuring that patient use of the device does not interfere with delivery of prescription medications.

(6)Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions.

(f) Written policies and procedures shall be maintained at least three years beyond the last use of an automated delivery device.

(g) For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.

Note: Authority cited: Sections 4005, 4075, and 4114 Business and Professions Code. Reference: Sections 4005, 4052, 4116 and 4117 Business and Professions Code.

Amend Section 1717 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1717. ~~Pharmaceutical~~ Pharmacy Practice.

(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.
Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:

(1) a patient med pak is reused only for the same patient;

(2) no more than a one-month supply is dispensed at one time; and

(3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."

(b) In addition to the requirements of Business and Professions Code Section 4040, the following information shall be maintained for each prescription on file and shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist ~~preceptor~~ before they are dispensed.
(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and
(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.
(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing.
Chart orders as defined in Section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.
(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005.
(e) ~~No licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.~~
~~However, a licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. The Board may in its sole discretion waive this application of the regulation for good cause shown.~~
~~(f)~~ A pharmacist may transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, 1306.26.
Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of Section 1716. Information maintained by each pharmacy shall at least include:
(1) Identification of pharmacist(s) transferring information;
(2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;
(3) Original date and last dispensing date;
(4) Number of refills and date originally authorized;
(5) Number of refills remaining but not dispensed;
(6) Number of refills transferred.

~~(g)~~ (f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

Note: Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116, 4117 and 4342, Business and Professions Code.

Attachment C

Comments Received from:

1. Bob Hansen, PharmD. Vice President Pharmacy Services Asteres Inc.
2. Kevin N. Nicholson, R.Ph, J.D. and Mary Staples, NACDS
3. Steven Gray, Pharm. D., J.D., Kaiser Permanente
   (Josh Room, Deputy Attorney General, Letter in response to Mr. Gray's letter.)
4. John Cronin, CPhA
5. Gary R. Solomon, R.Ph.
6. Shane Gusman, United Food & Commercial Workers
7. Fred S. Mayer, R.Ph., M.P.H. President, PPSI

January 12, 2006

Patricia Harris
Executive Officer
California State Board of Pharmacy
1625 North Market Boulevard, Suite N219
Sacramento, CA 95834

Ms. Harris:

Asteres Inc. appreciates the on-going interest the Board has had in ScriptCenter®, a prescription refill delivery kiosk. We have made efforts to ensure the Board is knowledgeable about the system, including having the Board visit our office for a demonstration back in July of 2004. Additionally, Asteres has solicited guidance from the Board to ensure our practices are consistent with your expectations.

Asteres has gained much experience since the initial installation in December, 2004, and believe the technology has performed well in the marketplace. Several State Boards have approved the use of ScriptCenter in their states; see attached document for details. The time is right for the Board to support the proposed regulation change that would allow usage of automated delivery devices without requiring each retailer to obtain a waiver. To that end, Asteres will share with the Board a summary of our experiences with ScriptCenter thus far.

- As of the end of 2005, there were seven ScriptCenters installed (Six in California and one in Virginia)
- Almost 5000 people have signed up to use ScriptCenter.
- Nearly 19,000 individual prescriptions have been delivered by ScriptCenter.
- Uptime during the first month of usage showed that ScriptCenter was up almost 99% of the time during store hours.

System performance has been very good, but there have been issues on occasion, most commonly:

<u>Unknown bag</u>

- Description: ScriptCenter cannot read the bar code on the ScriptCenter bag, usually due to a bar code scanner failure.
- ScriptCenter Action: The bag is moved to a specific tray, and ScriptCenter goes out of service.

<u>Bag stuck on hooks</u>

- Description: A bag is stuck on the hooks and is not moved to its intended location. This is usually due to a bar code scanner failure, though sometimes it is a general hardware failure.

- ScriptCenter Action: The bag is left on the hooks, and ScriptCenter goes out of service.

Failure moving bag:

- Description: ScriptCenter occasionally fails when moving bags within the machine.
- ScriptCenter Action: ScriptCenter automatically goes out of service and remains out of service until the bag in question is removed by the pharmacy staff.

In each of the cases above, the pharmacy staff must remove the bag before the system can go back in service. Asteres treats every system issue very seriously, and continues to improve the reliability of ScriptCenter.

Asteres is very interested in consumer reaction to ScriptCenter. Over 80 customers have completed a survey about ScriptCenter, with the results being very positive. For all three of the following questions, the average response was somewhere between the two highest measures:

- How satisfied are you with ScriptCenter?
- How likely is it that you will use ScriptCenter after hours (when the pharmacy is closed)?
- Would you recommend ScriptCenter to others?

Customers have included comments on their surveys as well:

"This is the best thing Longs could have done. I hope other pharmacies follow. Thank you!"

"New prescriptions, please."

"I have now used the ScriptCenter twice and have found it to be a quick, no-nonsense alternative to standing in line for refill prescriptions."

ScriptCenter technology has been positively received by both consumers and retailers alike. While the system has occasional failures, in none of the almost 18,000 transactions has ScriptCenter delivered a wrong prescription to a consumer. Asteres urges the Board to approve the regulation change to prevent barriers to using this beneficial new system.

Sincerely,
Bob Hansen, PharmD.
Vice President Pharmacy Services
Asteres Inc.

State Board of Pharmacy Approvals and Conditions
Granted to Asteres Inc. as of December 31, 2005
Provided to the Board by Bob Hansen, PharmD, Asteres Inc.

CALIFORNIA: currently granting waivers to allow refill prescriptions not requiring consultation. The waiver also allows for prescription pick-up even if the pharmacy is closed providing the patient can receive a consultation on his or her medications when the pharmacy is closed.

HAWAII: currently may be used for new or refill, non-scheduled drug prescriptions that do not require the offer of consultation (OBRA 90 patients). The machine can only be used when the pharmacy is open.

VIRGINIA: has granted a one store pilot to use ScriptCenter for refills only. The pilot allows for prescription pick-up if the pharmacy is closed provided a patient can receive a consultation on his or her medications when the pharmacy is closed.

NEW YORK: may be used for refill prescriptions of non-scheduled drugs, but only when the pharmacy is open.

OHIO: pending a final inspection ScriptCenter can be used under the following conditions: (1) it is to be accessible only when the pharmacy department is open for business. (2) Access to the machine by both staff and patients must be in compliance with the board's definition of positive identification (4729-5-01(N)OAC). (3) Controlled substances may be included in the medications in the machine. (4) The system may be used for both new and refill prescriptions. (5) The system must be physically attached to the Pharmacy Department with access only from inside the business. (6) The system must comply with all of the Board's record keeping requirements. (7) The offer to counsel must occur after the patient selects the products to be obtained.

MARYLAND: Ahold had requested to be able to use ScriptCenter for all prescriptions and to be able to deliver prescriptions only when the pharmacy was open. The Board's response was "As long as a pharmacist is present, the ScriptCenter device appears to be in compliance with the Maryland Pharmacy Act".

April 5, 2006

Patricia Harris
Executive Officer
California State Board of Pharmacy
1625 North Market Boulevard, Suite N219
Sacramento, CA 95834

Ms. Harris:

Asteres Inc. appreciates the on-going interest the Board has had in ScriptCenter®, a prescription refill delivery kiosk. We have made efforts to ensure the Board is knowledgeable about the system, including having the Board visit our office for a demonstration back in July of 2004. Additionally, Asteres has solicited guidance from the Board to ensure our practices are consistent with your expectations.

Asteres has gained much experience since the initial installation in December, 2004, and believe the technology has performed well in the marketplace. Six other State Boards have approved the use of ScriptCenter in their states, and additionally three other State Boards are considering new regulations in support of ScriptCenter use (see attached document for details). The time is right for the Board to support the proposed regulation change that would allow usage of automated delivery devices without requiring each retailer to obtain a waiver. To that end, Asteres will share with the Board a summary of our experiences with ScriptCenter thus far.

- As of April 1, 2006, there were nine ScriptCenters installed (eight in California and one in Virginia)
- Over 6,800 people have signed up to use ScriptCenter.
- Nearly 33,000 individual prescriptions have been delivered by ScriptCenter.
- Uptime during the first month of usage showed that ScriptCenter was up almost 99% of the time.
- 51% of prescription pick-ups are between the hours of 3:00 PM and 7:00 PM.
- 56% of the registered users are 51 years of age or older, with 7% over the age of 65.

Asteres is very interested in consumer reaction to ScriptCenter. Over 80 customers have completed a survey about ScriptCenter, with the results being very positive. For all three of the following questions, the average response was somewhere between the two highest measures:

- How satisfied are you with ScriptCenter?
- How likely is it that you will use ScriptCenter after hours (when the pharmacy is closed)?
- Would you recommend ScriptCenter to others?

Customers have included comments on their surveys as well:

"This is the best thing Longs could have done. I hope other pharmacies follow. Thank you!"

"I have now used the ScriptCenter twice and have found it to be a quick, no-nonsense alternative to standing in line for refill prescriptions."

ScriptCenter technology has been positively received by both consumers and retailers alike. In none of the almost 33,000 transactions has ScriptCenter delivered a wrong prescription to a consumer. Asteres urges the Board to approve the regulation change to prevent barriers to using this beneficial new system.

Sincerely,

Bob Hansen, PharmD.
Vice President Pharmacy Services
Asteres Inc.

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

April 14, 2006

Ms. Patricia Harris
California State Board of Pharmacy
1625 North Market Blvd, Suite N219
Sacramento, CA 95834

Dear Ms. Harris:

RE: Proposed Regulation Section 1713, Receipt and Delivery of Prescriptions

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

On behalf of our 31 member companies operating approximately 3,122 chain pharmacies in the State of California, the National Association of Chain Drug Stores (NACDS) appreciates the opportunity to submit comments for the Board of Pharmacy's ("Board") consideration on the amended proposed Title 16, Section 1713 regulation on receipt and delivery of prescriptions.

Under proposed new Section 1713, the Board aims to allow a patient to deposit a prescription in a secure container for retrieval by pharmacy personnel, and to allow a pharmacy to use an automated device to dispense refilled prescriptions so long as certain, specific conditions are met.

We applaud the Board's proposal. Prescription volume continues to grow; however, the number of licensed pharmacists is not keeping pace with the growing demand for pharmacy services. Pharmacies and pharmacists are seeking ways to meet this increasing demand, including using technology solutions. The volume of prescriptions filled by community pharmacies has risen dramatically over recent years from 2.78 billion in 1998 to more than 3.2 billion per year in 2004. Prescription volume is expected to continue to increase significantly with the new Medicare drug benefit law, along with an aging population and the expected increased use of prescription drugs in this population. Between 2004 and 2010 the supply of all community pharmacists is expected to increase only 7.8% vs. an estimated 27% increase in number of prescriptions dispensed, going from 3.27 billion in 2003 to over 4.1 billion in 2010.[1] We believe that the Board's proposed rule will greatly assist pharmacies and pharmacists in meeting the demand for pharmacy services.

(703) 549-3001
Fax (703) 836-4869
www.nacds.org

[1] Source: NACDS Economics Department

We believe the Board's proposed rule will benefit patients, as well. In our busy and hectic society, consumers appreciate streamlined services that make the best use of their time. Under the Board's proposed rule, patients will be able to drop off prescriptions at the pharmacy when it is convenient for them, even when the pharmacy is closed. Moreover, they will be able to drop off prescriptions without having to wait in line when the pharmacy is open.

Prescription refills do not usually require patient counseling. Patients picking up prescription refills will be able to do so without waiting in line behind patients being counseled. They will be able to pick up prescription refills even when the pharmacy is closed. Of course, counseling would be provided via telephone upon request.

For the benefit of both consumers and pharmacists, we urge the Board to adopt Rule 1713. Thank you for your consideration of our comments.

Sincerely,

K Nicholson Mary Staples

Kevin N. Nicholson, R.Ph, J.D.
Vice President, Pharmacy Regulatory Affairs

Mary Staples
Regional Director, State Government Affairs

KAISER PERMANENTE®
Medical Care Program, California Division

Divisional Pharmacy Operations
Pharmacy Professional Affairs
12254 Bellflower Blvd, 2nd floor,
Downey, California
90242

March 3, 2006

Patricia Harris, Executive Officer
California State Board of Pharmacy
1625 North Market Blvd. Suite N219
Sacramento, CA 95834; FAX (916) 574-8618 RE: **Proposed Regulation 1713**

Dear Executive Officer Harris

We respectfully offer the following comments regarding the Proposed new pharmacy regulation 1713.

1. The proposed language limits the use of an "automated delivery device" [see subsection (d)] to "refilled prescription medications" and the term "refill" is used elsewhere in the proposed regulation. It is our understanding that the purpose of this limitation is to facilitate the requirement for the pharmacy to provide each patient the opportunity for personal consultation with a pharmacist as required by Pharmacy Regulation 1707.2.
In California it is commonly said that such consultation is required whenever there is a "new" prescription or when in the pharmacist's professional judgment it is deemed appropriate [subsection (a)(2)] and the patient has not refused such consultation [subsection (e)]. However, the term "new" is not used in the regulation. When that regulation was adopted the Board was advised and it agreed not to use either the terms "new" or "refill/refilled" prescription because those were not only confusing* but were technically inconsistent with the fundamental purpose, i.e. to explain to a patient important information about medication the patient had not had before. Therefore Regulation 1707.2 (b)(1) uses the following phrases:

> "(A) whenever the prescription drug has not previously been dispensed to a patient; or
> (B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy."

* The confusion arises out of the common practice of considering any dispensing of medication under a "new" prescription number as a "new" prescription even though the patient may have been provided the exact same medication, in the exact same strength and dosage form, with the exact same directions for use for many, many years. Consequently, a subsequent dispensing that is exactly the same as a previous dispensing except for the issuance of a new prescription number should be considered a "refill" under the intent and purpose of proposed regulations 1707.2 and proposed regulation 1713. Therefore, in order to avoid a legal confusion, we submit that proposed regulation 1713 should have all references to refill/refilled prescriptions either removed and substituted with the language above or the proposed regulation should define refill for the purpose of this regulation the same as it is defined above in regulation 1707.2.

2. The proposed regulation 1713 uses the phrase "adjacent to the licensed pharmacy counter" in subsection 1713(d)(6). The envisioned setting behind this choice of words was probably that of a common "chain" store where the licensed pharmacy area is separated by only a "counter" from the rest on the retail establishment's common area. The apparent intent is to require placement of the devices within a close geographic area under the assumption that closeness facilitates consultation with a pharmacist when there is a pharmacist on duty inside the licensed pharmacy area. Closeness is a factor but requiring the device to literally be "adjacent" may not be necessary to achieve the goal and may interfere with the Board's intent to provide greater patient access. As lack of restrictive wording in the proposed regulation demonstrates, the Board intends, and public discussion supported, the ability to employ these devices for delivery of medication to patients "after hours", i.e. when the licensed pharmacy area is closed and there or no pharmacist on duty. For example, even when under the new legal provisions the pharmacist is allowed to leave personnel in the pharmacy while on a 30 minute meal break.

In many medical facilities the general medical reception and waiting area is located just outside the licensed pharmacy but not necessarily "adjacent to the licensed pharmacy "counter" because the pharmacy's licensed area may include its own small waiting areas or an area for private consultation. The device may need to be located at the interface between the general medical reception and waiting area and the waiting/consultation area within the licensed pharmacy space. Such interface area is still

reasonably close to the pharmacist to allow consultation. The use of the phrase "adjacent to the licensed pharmacy counter", or a strict interpretation of its use, may interfere with this appropriate and convenient use of the devices in such facilities. If the device is truly "adjacent to the licensed pharmacy counter" and therefore within the licensed pharmacy, patients may not be able to use it when the pharmacy is closed. We therefore recommend modification of subsection 1713(d)(6) to describe more specifically the intent of the placement rather than only incorporating the phrase "adjacent to the licensed pharmacy counter" in such a short description. We suggest the following substitute language.

> "(6) The device is located in the facility as near as possible to the pharmacy counter to provide reasonably prompt access to a consulting pharmacist on duty, while, if desired, allowing the device to be used in the facility after pharmacy business hours or when no consulting pharmacist is on duty in the pharmacy."

This type of language would also remove ambiguity about the ability to use the device "after hours".

Sincerely

Steven W. Gray, Pharm.D., J.D.
Divisional Pharmacy Professional Affairs, (562) 658-3663

californiapharmacistsassociation

April 10, 2006

Jan E. Perez
California Board of Pharmacy
1625 North Market Blvd, Suite N219
Sacramento CA 95834
via e-mail

re: Comments on Proposed Regulation, Section 1713 and 1717 of Title 16

Dear Ms. Perez:

Enclosed please find CPhA's comments on the proposed regulation regarding Prescription Drop Boxes and Automated Delivery Devices.

As noted in the comments, I have also attached a copy of our comments submitted for the regulation hearing in October which dealt with the same topic. It is our wish that these earlier comments be incorporated by reference so that they are included in the regulation package that will be forwarded to the Office of Adminstrative Law should this language be adopted by the Board.

Let me know if you have any questions regarding this submission. I can be reached at (760) 432-0350.

Sincerely,

John Cronin

John Cronin, Pharm.D., J.D.
For the California Pharmacists Association

Comments on Proposed Regulation
Sections 1713 and 1717 of Title 16
Prescription Drop Boxes and Automated Delivery Devices
Submitted by
The California Pharmacists Association
April 10, 2006

Introduction

The Board is proposing to amend Section 1717 and add Section 1713. The Amendment to 1717 essentially removes certain provisions regarding receipt and delivery of prescriptions, which are then addressed in the proposed new section 1713. This proposal is the next step in the Board's consideration of the use of automated delivery devices in retail pharmacies. These machines are intended to be used both when the pharmacy is open and when the pharmacy is closed. In recent months, the Board has considered waiver requests from several pharmacies to install these devices to provide patients with access to refilled prescriptions without interaction with pharmacy personnel. In sharply divided votes, the Board has granted waiver requests for the use of these devices to Longs Drugs, the UCSD Medical Center, Safeway, Walgreens and the White Cross Drug Store of San Diego.

At its October 2005 Board meeting, the Board considered and rejected an earlier regulation proposal on the same subject. This proposed regulation represents a modification of the earlier language with changes intended to address concerns raised at the October regulation hearing.

We have provided, as an attachment, CPhA's comments regarding the October 2005 proposal. As there is no indication in these regulation materials that our earlier comments will be included in this regulation package, we feel it is important that those comments be included here. We encourage Board members to re-read those comments as they continue to be relevant to consideration of the revised language here.

General Comments

CPhA recognizes the need to promote the use of new technologies in the business and profession of pharmacy. This has been our position throughout the now lengthy debate about the use of automated drug delivery devices. We also agree with the Board that some form of regulation is needed to address the administrative burden associated with the waiver process the Board has used to deal with requests to use these devices. The question for CPhA is whether this regulation language reaches a proper balance of the risks and benefits to consumers and the provision of health care associated with the use of this technology.

The proposed regulation goes a long way toward addressing the issues that CPhA has raised throughout this process. We believe the Board and the manufacturers of these devices have made a serious and good faith effort to deal with our concerns. However, we continue to have concerns about the impact that the use and potential misuse of these devices will have on the proper delivery of health care and the role pharmacists will play in the future.

Comments on the Board's Proposed Language

Amendments to Section 1717

CPhA has no objections to the proposed amendments to section 1717. We agree that the issues being addressed here should be pulled from section 1717 and incorporated into separate new regulation sections.

New Section 1713

CPhA does not object to the Board's proposed language for sections 1713(a) thru (c), including the new subsection (c), which deals with secure containers for depositing prescriptions.

For the reasons we provided in our comments at the October 2005 regulation hearing, we continue to have concerns that the Board's proposed sections 1713(d) and 1713(e) do not strike the appropriate regulatory balance. As we did with the prior regulation proposal, CPhA believes the Board should require pharmacies to provide more specific statements of how the use of these devices will further a high standard of patient safety, promote good patient care and advance pharmacist-patient communication.

The basis of our concern is that a driving force for this regulation appears to be the Board's desire for a system to allow use of these devices that reduces the current administrative burden on the Board and its staff. As our approach is for a system that requires some review of the request prior to approval, we believe that further discussion will not produce any consensus as to acceptable language. Should the Board desire to explore this issue further, we will be happy to participate.

Unfortunately, if the concerns we have raised eventually are realized, it will be much more difficult for the Board to rectify the situation than it is for them to deal with it now. The Board's reluctance to give serious consideration to CPhA's proposals is a source of frustration for us, particularly in light of the Board's published Vision Statement, Mission Statement and Strategic Plan.

Technical changes
Section 1713(d)(5) reads:
"The pharmacy provides a means for each patient to obtain an immediate *via telephone or in-person consultation with a pharmacist if requested by the patient.*

For clarity, we suggest this be reworded to:
"The pharmacy provides a means for each patient to *request and obtain an immediate consultation with a pharmacist, either in-person or via telephone."*

Conclusion
CPhA recognizes the benefit of new technologies to pharmacy practice and agrees that these automated drug delivery devices can provide consumers with safe, convenient and cost effective access to their prescription refills. The Board's regulation of the use of these devices should promote not only administrative efficiency but also advance public health and consumer safety. In our view, this language falls short of that goal.

Comments on Proposed Regulation
Sections 1713 and 1717 of Title 16
Prescription Drop Boxes and Automated Delivery Devices
Submitted by
The California Pharmacists Association
October 7, 2005

Introduction
The Board is proposing to amend Section 1717 and add Section 1713. The Amendment to 1717 essentially removes certain provisions regarding receipt and delivery of prescriptions, which are then addressed in the proposed new section 1713. This proposal is the next step in the Board's consideration of the use of automated delivery devices in retail pharmacies. These machines are intended to be used both when the pharmacy is open and when the pharmacy is closed. In recent months, the Board has considered waiver requests from several pharmacies to install these devices to provide patients with access to refilled prescriptions without interaction with pharmacy personnel. In sharply divided votes, the Board has granted waiver requests for the use of these devices to Longs Drugs, the UCSD Medical Center, Safeway, Walgreens and the White Cross Drug Store of San Diego.

History
In 2004, the Board's Enforcement Committee was asked by Longs Drugs for a waiver under section 1717(e) to allow the installation of a ScriptCenter device in its store in Del Mar, California. The ScriptCenter is developed by Asteres, Inc., which is also located in Del Mar and whose founder is Linda Pinney, who happens to be a patron of the Longs Pharmacy involved in this initial request. Longs also requested a waiver to allow the use of a secure drop-box for prescriptions and refills. At the same meeting, the Board unveiled proposed regulation language to allow the use of these devices without having to go through the waiver process.

The California Pharmacists Association (CPhA) was present at this meeting and we raised several concerns about this technology and its use that we felt needed to be addressed. In particular, we expressed concern about the decreased interaction between the consumer and the pharmacist. We noted that the Board has spent considerable effort and resources over the last 10 years to promote interaction between consumers and pharmacists. In fact, the Board's logo is an image of two people engaged in conversation and advises consumers to "Be Aware, Take Care – Talk to your Pharmacist!" These efforts have won the Board national recognition in the form of multiple awards from the National Association of Boards of Pharmacy. Others at the meeting also raised concerns, included one pharmacist who opined that the unregulated use of these devices would be the antithesis of everything for which the Board currently stood.

The Board committee's response was that the Board also wanted to encourage the use of new and more efficient technology that could improve the drug delivery process while

protecting public safety. With that in mind, the committee referred the regulation language and Long's request for waiver to the full Board for consideration.

When considered by the Full Board, Longs had clarified its waiver request to ensure that it extended to the entire Longs chain and that request was approved by the Board. The Board chose to defer the regulation language until the future, pending collection of information about the use and utilization of the ScriptCenter in the Del Mar Longs. At subsequent Board meetings, Safeway, UCSD Medical Center and Walgreens all sought, and were granted, waivers to install the ScriptCenter Device and White Cross Drug Store in San Diego was granted a waiver to install a competing device, made by ddn Corp. Throughout this entire process, CPhA continued to raise its concerns about the way the Board would oversee the way these devices were being used. Despite our concerns, the Board decided to move forward with the same regulation language that had been proposed in 2004.

Shortly after the first request by Longs Drugs, Asteres, Inc. invited CPhA to visit its facilities and learn more about the Asteres ScriptCenter. This visit led to a very productive exchange between CPhA and Asteres about these devices. Later, CPhA met with pharmacy management from the UCSD Medical Center about their waiver request, which ultimately included performance of a study about the use of the ScriptCenter and consumer interaction with the device. (The study has not yet been done) CPhA has had additional contact with Asteres and UCSD about the regulation and the use of drug delivery devices such as the ScriptCenter.

In general, our improved understanding of the Asteres ScriptCenter and its competitor from ddn Corp. have led CPhA to recognize that our concerns are not with the technology itself, but with the way the technology could be used. We believe that our initial concerns about patient-pharmacist interaction continue to be valid; however, we recognize that this technology has a place in the delivery of medications to patients, particularly in the current economic environment for healthcare. We believe that our ongoing concerns justify a moderate level of regulation of the use of these devices by the Board - a level that is higher than that proposed by the Board.

Comments on the Board's Proposed Language
Amendments to Section 1717
CPhA has no objections to the proposed amendments to section 1717. We agree that the issues being addressed here should be pulled from section 1717 and incorporated into separate new regulation sections.

New Section 1713
CPhA does not object to the Board's proposed language for sections 1713(a) thru (c), including the new subsection (c), which deals with secure containers for depositing prescriptions. CPhA believes the Board's proposed regulation language in 1713(d) does not strike an appropriate degree of regulation for drug delivery devices. We proposed that the Board's language for section 1713(d) be amended and that a new section 1713.5 be added to deal specifically with these drug delivery devices.

Proposed Alternative Regulation Language

(a) New section 1713(d)

CPhA's proposal takes the Board's proposed new section 1713 and incorporates into it a new subsection (d) to retain the waiver system and reference the simplified waiver process for drug delivery devices described in our proposed new section 1713.5. The language proposed by the Board to deal with these devices (contained in the Board's proposed 1713(d)) is incorporated as part of our section 1713.5.

CPhA believes this is necessary to balance the interests of administrative simplicity and protection of the public interest. The Board's proposed language clearly favors a system that reduces the administrative burden on the Board and its staff. CPhA believes this goes too far and risks compromising the public safety in the use of these devices. In reaching this conclusion, we reference many of the media reports about these devices and note that Business and Professions Code Section 4118 establishes the standard for waiver of licensure requirements as: " . . . a high standard of patient safety, consistent with good patient care . . . ." CPhA believes that the same standard should apply to use of drug delivery devices and that the appropriate means to achieve this is through a waiver process.

(b) New Section 1713.5

At the same time that we propose some form of waiver process as necessary, we recognize that the current system, which requires full board action, is overly burdensome and unnecessary. What we propose is a simplified waiver process that will make utilization of these devices easier to authorize while maintaining regulatory oversight that does not endanger public safety nor compromise good patient care. At the same time, we believe the burden imposed by our proposal is both *reasonable* in its scope and *reasonably attainable* in its execution.

Our proposal introduces the concept of a "Pharmacy Services Plan," which is a written document, submitted by the pharmacy and approved by the Board, and which details how the device will be used, the impact such use will have on pharmacist-patient contact and how the use of the device will contribute to a high standard of patient safety consistent with good patient care. [1713.5(a)] The proposal lists components that must be addressed in the pharmacy service plan, but does not establish criteria for approval or disapproval by the Board. [Proposed 1713.5(b)]

It is our intent that the pharmacy services plan will provide some clear indicators of how the device will be used which will establish parameters for evaluation by the Board in its oversight role. Two "requirements" that are incorporated into the proposal at this point are that the device must be located "adjacent" to the licensed pharmacy area and that the pharmacy is responsible for the prescriptions stored in the device and the generation and maintenance of records regarding drugs placed in and removed from the device. These requirements should not be controversial as they are either included in the Board's proposed language or are a restatement of existing law.

Our proposal includes requirements for any pharmacy that employs a drug delivery device [1713.5(c)]. These provisions should not be controversial as they are restatements or minor elaborations of provisions in the Board's proposed language.

Section 1713.5 (d) thru (i) are based on discussions among a small group of stakeholders who met to discuss a possible consensus proposal for regulation of these devices. Although complete consensus was not reached, these sections reflect areas that all involved felt should be addressed in the regulation.

- 1713.5(d) Addresses the applicability of a pharmacy services plan to multiple sites under common ownership. This provision was felt to be reasonable and necessary to avoid excessive cost for applicants and the Board.
- 1713.5(e) requires the Board to take action on a submitted pharmacy services plan within 60 days or have the plan deemed approved. This provision is necessary to avoid unreasonable delays in plan approval that may occur due to factors beyond the control of the pharmacy submitting the plan.
- 1713(f) requires the pharmacy to update or affirm the pharmacy services plan at least annually or within 30 days of any change that substantially affects the standard of patient safety that is required for approval of a waiver. This provision is necessary to inform the Board of any issues that may result in an inspection of the pharmacy regarding the drug delivery device or that would initiate review of the waiver.
- 1713(g) thru (i) are provisions that were felt to be necessary to ensure adequate Board oversight of the waiver process and the ongoing use of the devices.

The advent of these devices may well drive a major reassessment of the role for pharmacists in the health care system. The need for devices like the Asteres ScriptCenter reflects a greater focus by society in general on reducing the costs associated with the provision of prescription medications. However, there is a real risk that this focus may reduce the impact of pharmacists on the selection and appropriate use of these medicines. The Board members should be well aware of the research data in the medical literature that supports the value of pharmacists in controlling not only drug costs, but also overall medical costs. These savings are realized not only through prudent efforts to control the cost of drug delivery to consumers, but also through appropriate utilization of prescribed medications.

It is often said that the most expensive medicine is the one that is never taken. Likewise, health care costs escalate when drugs are taken inappropriately. Many pharmacists currently play a key role in monitoring the appropriate use of prescription drugs. While few in the profession would argue that pharmacists cannot do a better job in this area, the reality is that the "job" is currently linked to the drug dispensing and delivery process. In considering any effort to deliver drugs more efficiently, the Board needs to consider what impact such change will have on the ability of pharmacists to provide their other skills and professional expertise to consumers.

These drug delivery devices bring to the consumer some added value over the existing system of drug delivery. The questions are, of what value and at what cost? The Board, in its Initial Statement of Reasons, states: "The board notes that use of self-services automated delivery devices has raised concerns among some individuals who see the machines being used to replace pharmacists and to reduce pharmacist consultation to patient." [sic] This is an overly broad generalization of the comments made by CPhA and others on this issue. The risk is not to jobs and consultations; it is to the opportunities for pharmacist-patient contact – what pharmacists see, hear and intuit that leads to a discussion with the patient about their medication use. Every pharmacist can give examples of this type of interaction – and the value of the resulting exchange between pharmacist and patient. The Board – consistent with its vision, mission and strategic plan - needs to ensure that use of any type of new technology does not compromise the opportunity for this type of interaction.

Without proper regulation, the use of these devices will be driven by the predominant factor in the healthcare marketplace today – cost. The impact could well be to break irrevocably the link between the pharmacist and the patient – the drug delivery process. The loss of that connection carries with it a potentially greater loss – the reduced possibility that, within the current healthcare system, pharmacists will eventually provide a much greater benefit to the overall health of the public. That benefit will come not only in the form of cost savings but also in the form of reduced medication side effects and better outcomes – exactly the "high standard of patient safety, consistent with good patient care" that should drive the Board's decision here.

CPhA's view is that the Board is well advised to move cautiously and should itself "Be Aware, Take Care" to ensure that consumers will continue to be able to "Talk to your Pharmacist." CPhA's proposed alternative provides a realistic alternative to the language proposed by the Board – which was drafted prior to having any experience with the use of these devices. It is clear that some modification of the Board's language is in order. We believe our alternative addresses the needs and concerns of all who have an interest in this issue.

Conclusion

CPhA recognizes the benefit of new technologies to pharmacy practice. However, the Board should not embrace these new technologies without considering all the impacts that may result. CPhA has proposed alternative language that provides a needed balance as this technology develops. It allows the advancement of technology without jeopardizing the pharmacist-patient relationship. We urge you to adopt our alternative and incorporate a simplified waiver process for pharmacies who want to use drug delivery devices.

Respectfully Submitted,

John Cronin, Pharm.D., J.D.
Senior Vice President and General Counsel

Alternate Language to that proposed by the Board for use drop off boxes and automated drug delivery devices
(changes to Board language in bold italics)

Adopt Section 1713 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1713. Receipt and Delivery of Prescriptions.

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services.

(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.

(d) *The Board may in its sole discretion waive the application of the regulation for good cause shown or pursuant to section 1713.5.*

Add a new section 1713.5

1713.5. Waiver Process for use of Devices to deliver refilled prescriptions; pharmacy services plan required.

A waiver to allow a pharmacy to use a device to deliver refilled prescriptions shall be granted provided the pharmacy complies with the following:

(a) the pharmacy submits and the board approves a pharmacy services plan regarding the location and operation of the device. For the purposes of this section, "pharmacy services plan" means a written plan that details how the device will be used, the impact such use will have on pharmacist-patient contact, and how the intended use of the device will contribute to a high standard of patient safety, consistent with good patient care.

(b) The pharmacy services plan required by this section shall provide, at a minimum:

1. *a description of how the pharmacy will determine appropriate patients to use the device;*
2. *that a pharmacist check the prescription prior to being placed in the device;*
3. *a description of the means available for the patient using the device to obtain a consultation with a pharmacist upon request;*
4. *a copy of the notice provided to patients when expected medications are not available in the device;*
5. *a description of pharmacy personnel that will be involved in (a) the preparation of and (b) the loading of, prescriptions that are placed into the device;*
6. *that the device is located adjacent to the licensed pharmacy area;*

7. *that the pharmacy is responsible for the prescriptions stored in the device and the generation and maintenance of records of drugs placed in and removed from the device;*

(c) Any pharmacy that employs such a device shall have and maintain:

1. *Proof of security measures adequate to prevent loss, theft, or misdelivery of any drugs maintained in the device;*
2. *Procedures for determining which prescriptions are appropriate to be placed in the device and for which patients, including whether consultation is appropriate;*
3. *Procedures to ensure the patient is aware of the availability of consultation;*
4. *A form, to be signed by the patient, consenting to the use of the device;*

(d) The pharmacy services plan required by this section may be applied to multiple locations owned by the same person or entity. Waivers granted pursuant to this section may extend to all locations covered by an approved pharmacy services plan.

(e) The board shall act to approve or disapprove a pharmacy services plan submitted pursuant to this section within 60 days of receipt. Failure by the board to take action within 60 days shall be deemed to be approval of the pharmacy services plan and the waiver.

(f) The pharmacy shall update or affirm the pharmacy services plan at least annually as part of the permit renewal process or within 30 days of any change in plan that substantially affects the high standard of patient safety, consistent with good patient care that is required to grant the waiver.

(g) The pharmacist-in-charge and permit holder shall be jointly responsible for compliance with this section. Records of compliance with this section shall be maintained for a period of three (3) years from making and may be maintained in electronic form provided that they are open to inspection, and printing of a hardcopy, at all times during business hours.

(h) Failure of the pharmacy to ensure use or performance of the device consistent with the pharmacy services plan and other provisions of this section shall be grounds for rescission of the waiver and disciplinary action.

(i) the board may refuse to allow a pharmacy to use a device (or more than one device) for good cause.

From the desk of Gary R. Solomon,R.Ph.

April 13, 2006

Jan E. Perez
California Board of Pharmacy
1625 North Market Blvd, Suite N 219
Sacramento, CA 95384

Re: Proposed Regulation 1713
Prescription Drop Boxes and Automated Delivery Devices

Dear Ms. Perez,

I am writing you as a concerned pharmacist who has spent over 30 years as a Community Pharmacist who is opposed to the current regulation but if the majority of the Board is determined to approve this regulation then I propose the following modifications as there are too many areas that are vague as written and need to be more defined and specific. Every licensed pharmacy applying to use these devices shall provide a concise policy and procedure with each application. The regulation shall include the following language and each applicants policy and procedure shall specifically address this criteria. It is my belief that the regulation's language is too vague and interpretation will vary significantly with each applicant's interpretation of this regulation. Here are my recommendations for modification and/or addition:

1713 (d):

(2) – Upon application, the critieria for patient use shall be specifically spelled out in the policy and procedure for operation and/or use of the device) established/drawn up by the pharmacy which is submitted and approved by the BOP prior operation of the machine and patient use.

(3) The policy for carrying out this procedure shall be included in the policy & procedure manual and submitted to the Board of Pharmacy with the application for review to insure that all laws and regulations are met prior to any approval.

(4) In addition to the proposed wording: Methodology and procedure for making this determination shall be outlined in the P&P and will insure that every refill order is reviewed by the pharmacist on duty before the orders can be installed in the device.

(6) instead of adjacent to the pharmacy: The device shall be located no further than 15 to 25 feet from the pharmacists filling station or pharmacists counseling station. The device shall be operational only during prescription services hours and only when a pharmacist is on duty.

(7) The policy and procedure manual shall spell out minimum requirements for securing the device to insure that it meets current laws and regulation. This will include who has internal access to the device, where the keys or lock combination for access are secured. If the device is serviced by a central fill or other remote delivery service to the pharmacy is the driver approved for access to the device or delivering to the pharmacy and leaving the refill orders in a secured lock box.

(8) **RESPONSIBILITY** – The Board needs to redefine existing laws and regulations. The pharmacists on duty should bear responsibility at store level if the supplies come from that store and the refill orders are filled with those supplies. If prescription orders come from outside facility, such as a central fill facility, there should be shared responsibility if the policy and procedure manual requires review of all orders being placed in the device prior to dispensing. If at store level the pharmacist staff is excluded from this process then the filling entity and pharmacy ownership shall bear all responsibility. (If such a policy were to be approved by the Board this would negate any chance for clinical intervention by the pharmacist staff thus nullifying the Board's intention to increase clinical intervention and patient contact with the pharmacist.)

(9) Any incident must be committed to writing with in 48 hours of the incident. A report shall be made to the Board of Pharmacy within 72 hours if incident caused hospitalization of the patient or an extreme level of medical intervention.

1713. (e) (7) Needs the role of the central fill facility included in this part of the operational policy.

Thank you for your help and consideration with these issues.

Sincerely,

Gary R. Solomon, R.Ph.
Consultant Pharmacist
25725 Demeter Way,
Mission Viejo, CA 92691
949-683-2114
rxfun@sbcglobal.net

LAW OFFICES OF BARRY BROAD

April 10, 2006

Jan E. Perez
California Board of Pharmacy
1625 North Market Blvd., Suite N 219
Sacramento, CA 95384

SENT VIA FACSIMILE: (916) 574-8618

Re: Proposed Regulation
Prescription Drop Boxes and Automated Delivery Devices—OPPOSE

Dear Ms. Perez:

I am writing on behalf of the United Food & Commercial Workers (UFCW) to oppose the above referenced proposed regulation. The UFCW, which represents pharmacists and pharmacy personnel in retail settings throughout California, is very concerned about the proposal's potential impact on patient safety and creation of liability for pharmacists.

The Pharmacy Board is charged with protecting the health and welfare of pharmacy consumers. It follows that any regulations promulgated by the Board would be guided by that purpose. Unfortunately, the proposed regulations seem to be driven by economics rather than patient health.

First and foremost, we are concerned that unlimited use of automated delivery systems will result in less interaction between the patient and pharmacist. While reducing lines at pharmacies is a worthwhile goal, that benefit hardly outweighs the potential negative outcomes when patients have difficulty consulting with a pharmacist. Providing the patient with a telephone number hardly ensures that there will be somebody else on the other line.

The proposed regulation is much too vague and fails to provide enough guidance in several key areas. The regulation should specify at a minimum what information should be provided in the patient's written consent. The regulation should specify what a pharmacy should communicate to patients concerning use of the machines and procedures when the devices malfunction.

The UFCW is also concerned about the potential licensure liability for pharmacists who have these devices where they practice. The devices will be placed in retail pharmacies not by the choice of the pharmacists but by the chain drug store management. Store management will choose where to place the device and which device to use. Yet, if the device malfunctions it will be the pharmacist's license that will be on the line. That is fundamentally unfair.

1127 11th Street, Suite 501
Sacramento, CA 95814
(916) 442-3999
Fax (916) 442-3209

To address the licensure issue we suggest two changes to the proposed regulation. First, make it clear that the pharmacist has complete discretion over what prescriptions are dispensed through these devices. In order to ensure discretion, the pharmacist should be protected from discipline or discharge from his or her employer for exercising their good faith professional judgment. There is precedent for this in the Business and Professions Code. Additionally, the pharmacist should be expressly immune from licensure sanctions if an automated delivery device malfunctions or an error results from the patient's use of the machine.

Thank you for your consideration of these very important issues.

Sincerely,

Shane A. Gusman
Attorney-at-Law
On Behalf of the
United Food &
Commercial Workers

pharmacists planning service, inc.
101 Lucas Valley Road, Suite 210 • San Rafael, California 94903
Tel: (415) 479-8628 • Fax: (415) 479-8608 • e-mail: ppsi@aol.com

April 17, 2006

Patricia Harris, Chief Executive Officer
California State Board of Pharmacy
Sacramento, CA

Dear Patty:

For your information, please read the following regarding obtaining Rx's from Kiosks:

PPSI asks the following questions for the next Board of Pharmacy meeting on kiosks which I believe is next week—

Will there be:

1. Kiosk refills for C3s, C4s and C5s in kiosks?

2. Black box warning on Rx's in kiosks?

3. Discretion of pharmacists - How? When? Where? What means?

4. A list of what drugs will not be put into kiosks such as Insulins, restricted drugs, FDA special warning drugs such as Accutane, etc.

5. A questionnaire or survey to patients and to pharmacists who do not wish to have kiosk prescriptions on their watch. If so, how will this be done. Please send me a copy of the questionnaire/survey or information sheet that is between management and the practicing pharmacist.

6. How will consultation issues work for those patients who want further consultation? We understand there will be an 800 telephone number. Who will be answering this phone number? Will someone be available after hours, Sundays, holidays, etc.?

I would like to attend next week's meeting. Please give me an approximate time when the kiosk issue will be heard on Wednesday, April 26th. Also, I would like to reintroduce all of the testimony from the October, 2005 hearing in Burlingame as I understand you have new regs and I have to reintroduce this issue so that the Office of Administrative Law (OAL) can look at it. Is this correct?

Please refer to my letter with exhibits dated Tuesday, October 25, 2005 which was presented at the Crown Plaza Hotel in Burlingame, California. Perhaps you can reintroduce this for me, print up the packet for the Board of Pharmacy group to make comments on prior to the meeting.

Also, I will fax you a copy of a March 14th letter from Senator Jackie Speier regarding Senate Concurrent Resolution (SCR 49) on prescription drug errors which has been put together by CPhA regarding the increase of Rx errors. I notice the California Board of Pharmacy does not have representative. I would like this copied and passed out as PPSI believes as a nonprofit consumer advocacy group that the BOP needs to be represented in the interest of public health safety and harm on this medication error panel.

Thanks for your assistance.

Sincerely,

Fred S. Mayer, R.Ph., M.P.H.
President, PPSI

pharmacists planning service, inc.
101 Lucas Valley Road, Suite 210 • San Rafael, California 94903
Tel: (415) 479-8628 • Fax: (415) 479-8608 • e-mail: ppsi@aol.com

California Board of Pharmacy Meeting
Tuesday, October 25, 2005; 1:30 p.m.
Crown Plaza Hotel, 1177 Airport Boulevard, Burlingame, California

Regulation Hearing - Prescription Drop Boxes and Automated Self-Use Delivery Devices for Refill Prescriptions
Proposed Amendment to Repeal 16 CCR Sec. 1717 and to add 16 CCR Sec. 1713

Testimony of Fred S. Mayer, R.Ph., M.P.H., President
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2. Bret Miller, Pharm.D., CPhA Trustee - Exhibit No. 2.

3. James Kramme, R.Ph., Exhibit No. 3.

4. Robert A. Reed, Pharm.D., Arroyo Grande, California, Exhibit No. 4.

5. Larry Sasich, Pharm.D., MPH, FASHP, PPSI's Expert in the MedGuide Field, Public Citizens, and Associate Professor, Lake Erie School of Pharmacy, Pennsylvania, Exhibit No. 5.

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   b. "Useful Drug Information: Twenty Years and Still Waiting" article from Drug Topics Magazine, July 7, 2003, Exhibit No. 7.

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6. Generic Drugs Sampled Freely in Aetna Test in Kiosks, Exhibit No. 16.

   a. Do MD's have to comply with standards for kiosk dispensing?, Exhibit No. 17.

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In summation, please notice Exhibit, No. 19, the poster put out by the California State Board of Pharmacy, entitled "Notice to Consumers: Before taking any prescription medicine, talk to your pharmacist; be sure you know:

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3. What are the possible side effects? What should I do if they occur?
4. Will the new Rx work safely with other Rx's, OTCs and other herbal medicines I am taking?
5. What foods, drinks or activities should I avoid while taking this Rx?

ASK YOUR PHARMACIST IF YOU HAVE ADDITIONAL QUESTIONS."

How do pharmacists do this when the Rx is dispensed from a kiosk?

Thank you for giving me the opportunity to present this testimony.

small Dubuque pharmacy suddenly was mailing out huge quantities of addictive drugs to addresses throughout the country.

Investigators raided the pharmacy, then tracked many of the drug orders to a Web site called BuyMeds.com. The site's owners allegedly paid physicians to write prescriptions based on electronic questionnaires that customers filled out from their home computers. Schwab admitted authorizing a total of more than 1 million doses of drugs requested via such Web sites. He admitted approving up to 200 orders per day, and receiving $8 for each one.

Three Iowa pharmacists surrendered their state licenses, but so far, only physicians have faced criminal charges in the investigation. The government's broad net represents an increasingly aggressive approach against doctors involved in Internet drug schemes, a national expert said. "This is one of the biggest, if not the biggest, case of this kind that we've seen," said Dale Austin, senior vice president of the Federation of State Medical Boards.

Stephanie Rose, an assistant U.S. attorney prosecuting the cases, said doctors can provide a veneer of legitimacy to unscrupulous Internet drug sites. "The hope of the Department of Justice is to stop the flow of legal drugs to the illegal market," she said in an interview. "Doctors are a big part of the legal market. We want to make sure they're not drawn into the illegal market."

Authorities say it is illegal for a doctor to prescribe drugs without examining patients or having a legitimate medical relationship with them. It also is illegal for consumers to buy such medicine without a valid prescription, but consumers rarely are prosecuted for making purchases from the growing array of Web sites offering Vicodin, Valium, Ritalin and other addictive drugs.

BuyMeds.com, which was owned by a company in the Virgin Islands, no longer sells drugs, but many other sites remain in business. Internet message boards are filled with boastful reports from the sites' customers. Here's one posted in 2003 by "Tyler," who related his experience buying the narcotic painkiller hydrocodone on BuyMeds.com. He ordered 60 pills on a Sunday night, and received them by Federal Express Wednesday morning, he said. "These will come in useful if ever I should run out of the Tylenol 3's my doctor prescribes. I have to say that out of the SIX internet pharmacies I have tried, they have ALL come through."

"Tyler" wrote that he spent $168 for the drugs. If he had brought a legitimate prescription for the same pills into an Iowa pharmacy, he could have bought them for about $35.

Urbandale pharmacist John Forbes said the fact that Internet customers will pay so much for the drugs implies they have addiction problems. "It runs up a big red flag to me," he said. Forbes applauded authorities for aggressively prosecuting the current case. "I think they're doing this to set an example. They want to put a stop to this."

Rose, the prosecutor, acknowledged that the government lacks resources to prosecute every customer who purchases pills illegally. "I don't think we're ever going to stop the addicts from wanting to buy them," she said. "All we can do is try to shut down the supply."

The leader of Iowa's largest doctors' group said he had no qualms about possible imprisonment for physicians in such cases. "This isn't about legitimate business. This is about drug-dealing," said Dr. Stephen Richards of Algona, president of the Iowa Medical Society.

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San Francisco, CA 94102
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SENATOR.SPEIER@SEN.CA.GOV

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California State Senate

SENATOR JACKIE SPEIER

REPRESENTING SAN FRANCISCO AND SAN MATEO COUNTIES

COMMITTEES

CHAIR
Banking, Finance and Insurance
Select Committee on Government Cost Control
Select Committee on Methamphetamine Abuse

MEMBER
Education
Joint Committee on Legislative Audit
Select Committee on Developmental Disabilities and Mental Health

March 14, 2006

Fred S. Mayer, R. Ph., M.P.H.
President, Pharmacists Planning Services, Inc.
101 Lucas Valley Road, Suite 384
San Rafael, CA 94903

Dear Fred:

Thank you for your interest in the Medication Errors Panel created by the passage of Senate Concurrent Resolution (SCR) 49 which I authored last year. I am pleased to provide you with an update about the activities related to the resolution for your meeting to be held on March 19, 2006.

The resolution, sponsored by the California Association of Pharmacists, creates a 17-member panel consisting of representatives of various stakeholder groups and members of the legislature. The panel is charged with producing a report with recommendations of ways to reduce the incidence of mediation errors.

The Speaker of the Assembly recently appointed the following persons to serve on the panel who represent the organizations or groups as required in the resolution:

- Assembly Member Wilma Chan, representing the Assembly Democratic Caucus;
- Assembly Member Greg Aghazarian, representing the Assembly Republican Caucus;
- Brian Alldredge, University of California, San Francisco, Professor of Clinical Pharmacy, a member of the faculty of a school of pharmacy;
- Carlo Michelotti; representing the California Pharmacists Association;

- Carey Cotterell, Kaiser Permanente, Medical Care Program, Pharmacy Quality & Patient Safety Leader, representing the California Association of Health Plans;
- Merrill Jacobs, representing the Pharmaceutical Research and Manufacturers of America (PhRMA);
- Dr. Gurbinder Sadan, a member of the California Medical Association;
- Ramon Castellblanch, San Francisco State University, Assistant Professor of Health Education, a consumer representative;

We are awaiting the Senate Rules Committee to appoint representatives of the following entities as specified in the resolution:

- A representative of the California Retailers Association Chain Drug Committee;
- A member of the California Society of Hospital Pharmacists;
- A representative of the Generic Pharmaceutical Association;
- A representative of a public health organization;
- A member of the California Nurses Association;
- A representative of AARP;
- A representative of the Consumer Health Care Products Association;
- A member or representative of the Senate Democratic Caucus
- A member or representative of the Senate Republican Caucus.

My staff has been working with the sponsor of the resolution, the California Pharmacists Association, to ensure that the appropriate funding for the panel is secured. As soon as the issues of funding and the appointments of members by the Senate Rules Committee are resolved, a meeting of the panel will be scheduled, and you and others will be notified about it.

If you or your colleagues would like additional information about the panel or want to ensure that you are on the list of people to be notified about future panel meetings and the work of the panel, please contact Ronald Spingarn at Ronald.Spingarn@sen.ca.gov or (916) 651 -4008.

Please keep up the good work that you are doing with the Pharmacists Planning Services and I look forward to working with you and your colleagues on this and other issues in the future.

All the best,

Jackie Speier

JACKIE SPEIER
State Senator,
8th Senate District

pharmacists planning service, inc.
101 Lucas Valley Road, Suite 210 • San Rafael, California 94903
Tel: (415) 479-8628 • Fax: (415) 479-8608 • e-mail: ppsi@aol.com

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Seventeen Fifty
Medical Center Pharmacy
INCORPORATED

1750 EL CAMINO REAL
BURLINGAME. CALIFORNIA 94010
PHONE (650) 692-1686
FAX (650) 692-0859

September 27, 2005

TO: FRED FAX: 415-479-8608
PAGES: 1

FROM: HARRY

I can't be at the Board of Pharmacy Public Hearing regarding the delivery devices. I have questions you may want to ask unless they already have been addressed.

The Board says, "automated delivery devices will provide consumers with greater access to picking up their refill prescriptions by allowing access both during regular pharmacy hours and when the pharmacy is closed".

a) Does "when the pharmacy is closed" mean the entire store or only the Rx department? If it is the entire store and the specific conditions state, "The automated delivery device is located adjacent to the licenced pharmacy", does that mean the device can be located next door at the Pizza Parlor?

b) If a patient picks up refills when the store is closed, then has a question about side effects after having taken the original Rx or finds one Rx is not what the patient ordered, how does the patient have access to a pharmacist?

From: Rsklotz
To: PPSI
Subject: Re: Bd. of Pharm.Hearing/Kiosk, Oct. 25th, 9 a.m. - 4 p.m., Crown Plaza, Burl...
Date: Mon, 3 Oct 2005 6:55:49 PM Eastern Daylight Time

I continue to see patients with problems/diseases induced by drugs. The approach of making much easier for the patient to get medications without a professional interaction should dramatically increase my business since there will probably be a further increase in "Drug Induced Disease". I want to thank everyone involved for helping my consulting business. Also, remember the caveat of "Let The Buyer Be Aware". The more prescriptions we fill the greater is the opportunity for adverse reactions. We is everyone going to learn to understand the true problem is not easy and more dispensing of drugs, but the real answer it to use drugs more carefully and with a great deal of skill. When I talk to physicians groups (surgeons in particular) I explain that the "Pharmacological Scalpel" must be used with the same level of skill that a surgeon uses with a surgical scalpel.

By the way I just got off the phone with a group that wants be to meet with a Oncology group practice regarding the dosing of drugs using pharmacokinetic models. It is interesting that a extremely specialized group of physicians are looking for help from a pharmacist and not to fill more prescriptions.

Just my thoughts and ravening's.

Roger Klotz

Exhibit 1

3

10-10-05

Dear Calif. State Board of Pharmacy,

As a pharmacist, I feel that Kiosks are bad medicine. Due to no counseling etc they are not in the best interest of the Publics health. It's time for the board to really consider what is in the best interest to the patient and not fall into "what is best for chain drug stores."

James Hamme RPh

NOTE!!

* Reject Safeway, Walgreens and Kaiser Board Members

Exhibit 3

Subj:	**Board of Pharmacy Proposed regulation RX drop boxes and Automated Delivery devices**
Date:	10/10/2005 8:35:40 AM Pacific Daylight Time
From:	fincutter@charter.net
To:	Patricia_Harris@dca.ca.gov

Sent from the Internet (Details)

Pharmacy Board Members,

As a Pharmacist in charge with 21 years of working the case experience I'm quite surprised by the Boards proposed change to add Section 1713 Receipt and Delivery of Prescriptions. I don't foresee any problems with the drop off portion of the addition you proposed and in fact it's a needed change. I believe that your proposed addition to allow for automated delivery devices on the other hand will lead to long term changes in access to pharmacists. In your statement of reason your analysis of the impact of these machines I believe is flawed. Has the Board considered that centrally filled prescriptions are going to be the majority of the prescription placed in these units? The Pharmacist in Charge I assume will have liability for these prescriptions and yet a Pharmacist at the pick up site will not have been involved anywhere in the process of filling or dispensing the prescription. In light of this, how can the Board claim that it won't have an impact on either the patient health or on the Pharmacy staff level? Interactions with the Pharmacist will be lessened by these delivery devices. What about OTC and Rx drug interactions that are often discovered when picking up prescriptions? During routine pick up of Prescriptions I'm interacting with my Patients, checking there health and in general making them feel comfortable interacting with me. When we take away this we are creating an impersonal event that weakens Pharmacist care. I believe that employers will use the central fill – automated delivery devices to cut staff that will further put stress on the pharmacist remaining. Please reconsider your proposed addition of Sec. 1713 as I believe it will have a negative impact on the general public health and safety which the Board of Pharmacy is mandated to protect.

Bret Miller, Pharm.D.

Exhibit 2

Robert A. Reed, Rph, PharmD

1570 W. Branch St.

Arroyo Grande, Calif. 93420

October 10, 2005

California State Board of Pharmacy

400 R. Street Suite 4070

Sacramento, Calif. 95814

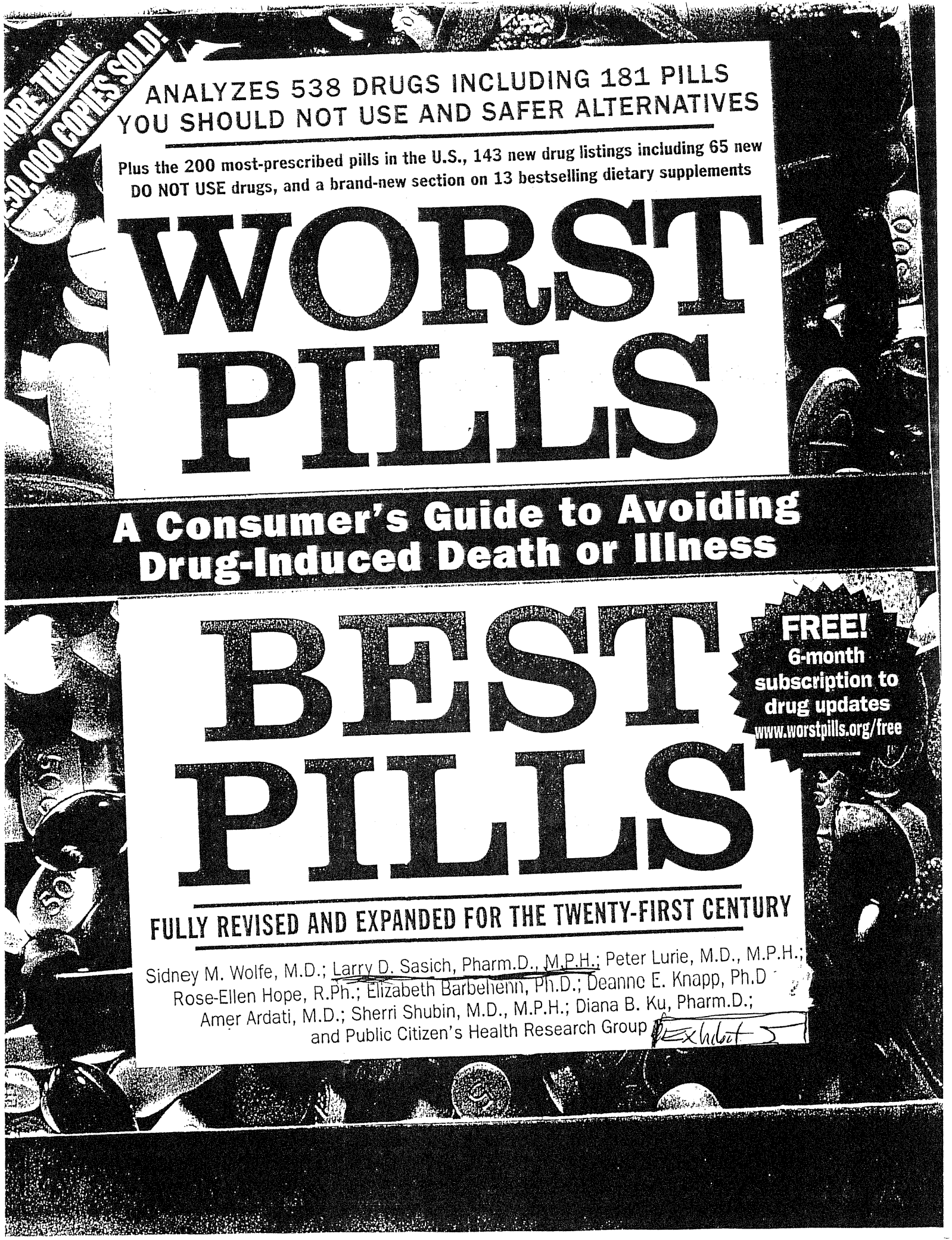
Pharmacy Board Members:

I have been a licensed practicing pharmacist in California since 1977 and in light of my experience would like to express my concerns regarding your proposed addition of Sec. 1713 to the current pharmacy law. Over the years, I have seen our profession pulled and tugged in many different directions. In my opinion this proposed change will take our profession in a drastically new and detrimental heading. I see it warping our effectiveness and usefulness in providing quality health care. Patient contact and accessibility is pharmacies most distinguishing aspect. We are available to all by simply allowing the patient to approach us with questions without a prior appointment and to help themselves to our knowledge and professional advice. This is how we are perceived and what the public expects from us and it is I believe, in large part why our profession has been held in such high esteem for so long by the public. I ask you to consider what is the driving force behind this new legislation. Who stands to gain? It is certainly not the public. The service they receive will lack our personal attention and contact and it will increase patient medication errors and dosing errors. Pharmacy will certainly not benefit. Employers will replace pharmacists with there new mechanized dispensers. Following the money trail leads me to believe that the push for this change is being led by those who will profit by it, namely the corporations which maintain pharmacies in there department stores such as Longs, Rite-aid, K-mart, CVS, Walgreen's, Costco and the like. To be blunt, I firmly believe that this legislation is being pushed through by corporate greed, with no thought of its effects on the quality of patient care or the future of the practice of our profession. If I were a betting man, regarding the adoption of Sec 1713, I would place my wager on the side with the power and the money, and that is unfortunate. It is my hope you will take these concerns to heart before you lead the parade over a cliff.

Respectfully,

Robert A. Reed, Rph, PharmD

Exhibit 4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Sidney M. Wolfe, M.D.; Larry D. Sasich, Pharm.D., M.P.H.; Peter Lurie, M.D., M.P.H.; Rose-Ellen Hope, R.Ph.; Elizabeth Barbehenn, Ph.D.; Deanne E. Knapp, Ph.D; Amer Ardati, M.D.; Sherri Shubin, M.D., M.P.H.; Diana B. Ku, Pharm.D.; and Public Citizen's Health Research Group
Exhibit 5

HEALTH

"More than 100,000 people a year die in American hospitals from adverse reactions to medication, making drug reactions one of the leading causes of death in this country."
—*Journal of the American Medical Association* study, as quoted in the *New York Times*

It is increasingly clear that certain drugs may have dangerous adverse effects, or that two relatively safe drugs, if taken together, can cause a fatal interaction. This indispensable, potentially lifesaving book gives you and your family—and your physician—the information you need about your medical treatment *before* you fill the prescription.

Top-selling drugs that are among the 181 DO NOT USE drugs discussed inside:

- Vioxx
- Yasmin
- Tricor
- Tussionex
- Avandia
- Actos
- Crestor
- Mobic
- Aricept
- Bextra
- Serzone
- Ultracet
- Celebrex
- Singulair
- Darvon/Darvocet
- Meridia

Patients fill over 130 million prescriptions a year for these 16 drugs at a cost of more than $11 billion!

Consumer advocate Sidney M. Wolfe, M.D., Director of Public Citizen's Health Research Group, and his colleagues have thoroughly revised this indispensable bestseller to include up-to-the-minute facts about the top-selling medications on the market today. *Worst Pills, Best Pills* contains startling information about certain well-known drugs that can cause *depression, hallucinations or psychoses, sexual dysfunction, dementia, auto accidents, insomnia, parkinsonism*, and more. It exposes drugs that simply do not work and others whose risks far outweigh the benefits.

Arranged by disease/condition, this easy-to-use guidebook offers chapters on adverse drug reactions, an alphabetical index that lists pills by their brand and generic names, new information about commonly used drugs, guidelines for helping you to say no if your doctor prescribes a drug you or your family should not take, and safer alternative choices. *Worst Pills, Best Pills* can help you to become actively involved in your own health care by knowing which questions to ask your physician, your pharmacist, and most important, yourself.

Caution: Call your doctor before stopping the use of any drug.

FREE! 6-month subscription to drug updates www.worstpills.org/free

It doesn't stop here! www.worstpills.org brings you this entire book—with frequent updates—as a searchable database. You also get:

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- **a six-month web subscription to *Worst Pills, Best Pills News* monthly newsletter**
- **analyses of pricing, advertising, and other drug-related issues**

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2

ADVERSE DRUG REACTIONS

How Serious Is the Problem and How Often and Why Does It Occur?

Although some adverse drug reactions (ADR) are not very serious, others cause the death, hospitalization, or serious injury of more than 2 million people in the United States each year, including more than 100,000 fatalities. In fact, adverse drug reactions are one of the leading causes of death in the United States.[1] Most of the time, these dangerous events could and should have been avoided. Even the less drastic reactions, such as change in mood, loss of appetite, and nausea, may seriously diminish the quality of life.

Despite the fact that more adverse reactions occur in patients 60 or older, the odds of suffering an adverse drug reaction really begin to increase even before age 50. Almost half (49.5%) of Food and Drug Administration (FDA) reports of deaths from adverse drug reactions and 61% of hospitalizations from adverse drug reactions were in people younger than 60.[2] Many physical changes that affect the way the body can handle drugs actually begin in people in their thirties, but the increased prescribing of drugs does not begin for most people until they enter their fifties. By then, the amount of prescription drug use starts increasing significantly, and therefore the odds of having an adverse drug reaction also increase. **The risk of an adverse drug reaction is about 33% higher in people aged 50 to 59 than it is in people aged 40 to 49.**[3,4]

Adverse Reactions to Drugs Cause Hospitalization of 1.5 Million Americans Each Year

An analysis of numerous studies in which the cause of hospitalization was determined found that approximately 1.5 million hospitalizations a year were caused by adverse drug reactions.[1] This means that every day more than 4,000 patients have adverse drug reactions so serious that they need to be admitted to American hospitals.

A review of patients admitted to medical wards of a hospital found that although for 3.8% of hospital admissions, adverse drug reactions led directly to hospitalization, 57% of these adverse drug reactions were not recognized by the attending physician at the time of admission. As in numerous other studies, many of these admissions should have been prevented. In fact, 18.6% of all drugs prescribed prior to admission were contraindicated.[5]

Another review of studies of the percentage of hospital admissions related to adverse drug reactions found that up to 88% of ADR-related hospitalizations in the elderly are preventable. In addition, elderly people were four times more likely to be hospitalized by ADR-related problems than nonelderly.[6]

Although the rate of drug-induced hospitalization is higher in older adults (an average of about 10% of all hospitalizations for older adults are caused by adverse drug reactions) because they use more drugs, a significant proportion of hospitalizations for children are also caused by adverse drug reactions.

A recent review of all studies concerning the reasons for pediatric hospitalization (children under the age of 19) found that 2.09% of all pediatric hospitalizations were caused by adverse drug reactions and that 39% of these were life-threatening.[7] Using the most recent published data on pediatric hospitalizations,[8] there were 3.8 million children under the age of 19 hospitalized in the United States in 1997. This means that in one year, there are 79,000 children (2.09% × 3.8 million children) admitted to the hospital because of adverse drug reactions, 31,000 of these children having life-threatening adverse reactions.

Adverse Reactions as a Major Cause of Emergency Room Visits

A recent review of studies concerning the causes of people going to hospital emergency rooms found that as many as 28% of all emergency department visits were drug-related, including a large proportion due to adverse drug reactions and inappropriate prescriptions. Of all of the drug-related visits, the authors found that 70% were preventable.[9]

Adverse Reactions Occur During Hospitalization to 770,000 People a Year

In addition to the 1.5 million people a year who are admitted to the hospital because of adverse drug reactions, an additional three-quarters of a million people a year develop an adverse reaction after they are hospitalized. According to national projections based on a study involving adverse drug reactions developing in patients in the hospital, 770,000 additional patients a year—more than 2,000 patients a day—suffer an adverse event caused by drugs once they are admitted. Many of the reactions in the patients studied were serious, even life-threatening, and included cardiac arrhythmias, kidney failure, bleeding, and dangerously low blood pressure. People with these adverse reactions had an almost twofold higher risk of death compared to other otherwise comparable hospitalized patients who did not have a drug reaction. Most important, according to the researchers, almost 50% of these adverse reactions were preventable. Among the kinds of preventable problems were adverse interactions between drugs that should not have been prescribed together (hundreds of these are listed in Chapter 3 of this book), known allergies to drugs that had not been asked about before the patients got a prescription, and excessively high doses of drugs prescribed without considering the patient's weight and kidney function.[10]

Thus, adding the number of people with adverse drug reactions so serious that they require hospitalization to those in which the adverse reaction was "caused" by the hospitalization, more than 2.2 million people a year, or 6,000 patients a day, suffer these adverse reactions. In both situations, many of these drug-induced problems should have been prevented.

Dangerous Prescribing Outside the Hospital for 6.6 Million Older Adults a Year

Based on the **Do Not Use** principle we have advocated concerning certain drugs for more than 16 years in our *Worst Pills, Best Pills* books and monthly newsletter, several published studies have examined the extent to which people are prescribed drugs that are contraindicated because there are safer alternatives. One study, whose authors stated that *"Worst Pills, Best Pills* stimulated this research," found that almost one out of four older adults living at home—6.6 million people a year—were prescribed a "potentially inappropriate" drug or drugs, placing them at risk of such adverse drug effects as mental impairment and sedation, even though the study only examined the use of a relatively short list of needlessly dangerous drugs (fewer than the number listed as **Do Not Use** drugs in this book).[11]

Other researchers looked not only at people for whom a contraindicated drug was prescribed, but also at prescriptions for older people involving two other categories: questionable combinations of drugs and excessive treatment duration. The authors categorized all of this as "high-risk prescribing" and limited their analysis to just the three classes of drugs most commonly causing drug-related illness: cardiovascular drugs, psychotropic drugs (ones that act on the mind) such as tranquilizers and antidepressants, and anti-inflammatory drugs. They found that 52.6% of all people 65 or older were given one or more prescriptions for a high-risk drug.[12] Thus, more than twice as many older adults were the victims of high-risk prescribing when these two additional categories were added.

Nine Reasons Why Older Adults Are More Likely Than Younger Adults to Have Adverse Drug Reactions

Many of the studies and much of the information concerning the epidemic of drug-induced disease focuses on people 60 and over. As we have mentioned previously, some of the changes that eventually lead to great numbers of adverse reactions in older adults (in combination with increased drug use) really begin to occur in the mid-thirties. In connection with the idea that drug-induced disease begins to get more common before age 60, it is interesting to note that in a number of studies comparing the way "older" people clear drugs out of the body with the way younger people do, the definition of older is above 50, and younger is below 50.[3]

1. Smaller Bodies and Different Body Composition: Older adults generally weigh less and have a smaller amount of water and a larger proportion of fat than younger adults. Body weight increases from age 40 to 60, mainly due to increased fat, then decreases from age 60 to 70, with even sharper declines from 70 on. Therefore, the amount of a drug per pound of body weight or per pound of body water will often be much higher in an older adult than it would be if the same amount of the drug were given to a younger person. In addition, drugs that concentrate in fat tissue may stay in the body longer because there is more fat for them to accumulate in.

2. Decreased Ability of the Liver to Process Drugs: Because the liver does not work as well in older adults, they are less able than younger people to process certain drugs so that they can be excreted from the body. This has important consequences for a large proportion of the drugs used to treat heart conditions and high blood pressure, as well as many other drugs processed by the liver. The ability of the body to rid itself of drugs such as Valium, Librium, and many others is affected by this decrease in liver function.

3. Decreased Ability of the Kidneys to Clear Drugs Out of the Body: The ability of the kidneys to clear many drugs out of the body decreases steadily from age 35 to 40 on. By age 65, the filtering ability of the kidneys has already decreased by 30%. Other aspects of kidney function also decline progressively as people age. This has an effect on the safety of a large number of drugs.

4. Increased Sensitivity to Many Drugs: The problems of decreased body size, altered body composition (more fat, less water), and decreased liver and kidney function cause many drugs to accumulate in older people's bodies at dangerously higher levels and for longer times than in younger people. These age-related problems are further worsened by the fact that even at "normal" blood levels of many drugs, older adults have an increased sensitivity to their effects, often resulting in harm. This is seen most clearly with drugs that act on the central nervous system, such as many **sleeping pills, alcohol, tranquilizers, strong painkillers such as morphine or pentazocine (TALWIN), and most drugs that have anti-**

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cholinergic effects (see *Anticholinergic* in the Glossary, p. 889). This latter group includes antidepressants, antipsychotic drugs, antihistamines, drugs used to calm the intestinal tract (for treating ulcers or some kinds of colitis) such as Donnatal, atropine, and Librax, antiparkinsonian drugs, and other drugs such as Norpace.

For all of the drugs in the above-mentioned groups that are listed in this book, we include an "anticholinergic" warning as follows:

> ANTICHOLINERGIC EFFECTS
>
> WARNING: SPECIAL MENTAL AND PHYSICAL ADVERSE EFFECTS
>
> Older adults are especially sensitive to the harmful anticholinergic (see Glossary, p. 889) effects of [name of drug class]. These drugs should not be used unless absolutely necessary.
>
> *Mental effects:* confusion, delirium, short-term memory problems, disorientation, and impaired attention.
>
> *Physical effects:* dry mouth, constipation, difficulty urinating (especially for a man with an enlarged prostate), blurred vision, decreased sweating with increased body temperature, sexual dysfunction, and worsening of glaucoma.

Yet another example of the marked increase in the sensitivity of older adults to drugs has to do with stimulant drugs that are in the same family as amphetamines, or "speed." Despite the dangers of these drugs for anyone, especially older adults, they are widely promoted and prescribed, including Ornade, Tavist-D, Entex LA, and Actifed. All of these contain amphetamine-like drugs such as pseudoephedrine. For any of these drugs discussed in this book, most of which are listed as **Do Not Use** drugs, the following warning is given:

> WARNING
>
> [Name of drug] can cause or worsen high blood pressure. It is especially dangerous for people who have high blood pressure, heart disease, diabetes, or thyroid disease. People over 60 are more likely than younger people to experience effects on the heart and blood pressure, restlessness, nervousness, and confusion.

5. Decreased Blood-Pressure-Maintaining Ability: Because older adults are less able to compensate for some of the effects of drugs, there is yet another reason why they are more vulnerable to adverse effects of drugs and more sensitive to the intended effects. The most widespread example of older adults' decreased ability to compensate is seen when they get out of bed and/or suddenly rise from a seated position. As you rise, your blood pressure normally falls, decreasing the blood flow to your head and resulting in less blood flow to the brain. Younger people's bodies can compensate for this: receptors in the neck, sensing that the blood pressure is falling as the person rises, tighten up the blood vessels in other parts of the body, thus keeping the overall blood pressure high enough. In older adults, these receptors do not work as well. Often, upon standing, older adults feel giddy, lightheaded, and dizzy. They may even faint because the blood pressure in the head falls too rapidly.

The ability to maintain a proper blood pressure is further weakened when you use any of a very long list of drugs, **the most common examples being high blood pressure drugs. Other categories of drugs that cause an exaggerated blood pressure drop include sleeping pills, tranquilizers, antidepressants, antipsychotic drugs, antihistamines, drugs for heart pain (angina), and**

antiarrhythmics. (See p. 31 for a full list of drugs that can cause this difficulty.)

This problem of so-called postural hypotension—the sudden fall in blood pressure on standing, brought about by a combination of aging and drugs—can be catastrophic. The falls that often result can end in hip fractures, a leading cause of death in older adults, or other serious injuries.

6. Decreased Temperature Compensation: Younger adults are more easily able than older people to withstand very high or very low temperatures. They sweat and dilate (widen) blood vessels to get rid of excess heat when it is hot, and constrict (narrow) blood vessels to conserve heat when it is cold. Older adults' bodies are less able to do this. As in the case of blood pressure compensation, this "normal" temperature-regulating problem of older adults can be significantly worsened by any of a large number of prescription and over-the-counter drugs, resulting in fatal or life-threatening changes in body temperature. **Many older adults' deaths during heat waves or prolonged cold spells can be attributed to drugs that interfere with temperature regulation. Most of these people did not know they were at increased risk.** All drugs in this book that contain a warning about anticholinergic effects can have this harmful effect on withstanding heat waves.

7. More Diseases That Affect the Response to Drugs: Older adults are much more likely than younger adults to have at least one disease–such as liver or kidney damage (not just the decreased function of older age), poor circulation, and other chronic conditions—that alters their response to drugs. Little is known about the influence of multiple diseases on drug effects in the elderly.

One well-understood example, however, is the effect of heart failure on the way people can handle drugs. When the heart is not able to pump as much blood as it used to, the change that occurs in heart failure, there is also a decrease in the flow of blood to the kidneys. For the same reasons discussed in reason number 3, the reduced flow of blood to the kidneys decreases the kidneys' ability to rid drugs from the blood and excrete them in the urine.

8. More Drugs and, Therefore, More Adverse Drug Reactions and Interactions: Since older adults use significantly more prescription drugs than younger people, they have greatly increased odds of having a drug reaction caused by the dangerous interaction between two drugs. Often, older adults take one or more over-the-counter drugs in addition to their prescription drugs. This further increases the likelihood of adverse drug interactions. One of the more common kinds of adverse drug interactions is the ability of some drug to cause a second drug to accumulate to dangerous levels in the body. At the end of the discussion of each drug in Chapters 4 through 28, except for the 181 **Do Not Use** drugs, there is a list of other drugs that can cause serious adverse interactions.

PARTIAL LIST OF DRUG INTERACTIONS

Some of these interactions are life-threatening or of great potential harm to patients. (See individual drug profiles for complete lists of interactions.)

TRICOR	with	LIPITOR
INSPRA	with	potassium
CELEBREX	with	warfarin (COUMADIN)
MEVACOR	with	LOPID
TEQUIN	with	BETAPACE
ALDACTONE	with	potassium
PROZAC	with	DESYREL
ULTRACET	with	PAXIL
insulin	with	INDERAL
TEGRETOL	with	erythromycin
TAGAMET	with	DILANTIN
GEODON	with	ZAGAM
INDERAL	with	TAGAMET
DEMEROL	with	NARDIL
CALAN SR	with	quinidine
theophylline	with	TAGAMET
warfarin (COUMADIN)	with	TAGAMET
LANOXIN	with	CALAN SR

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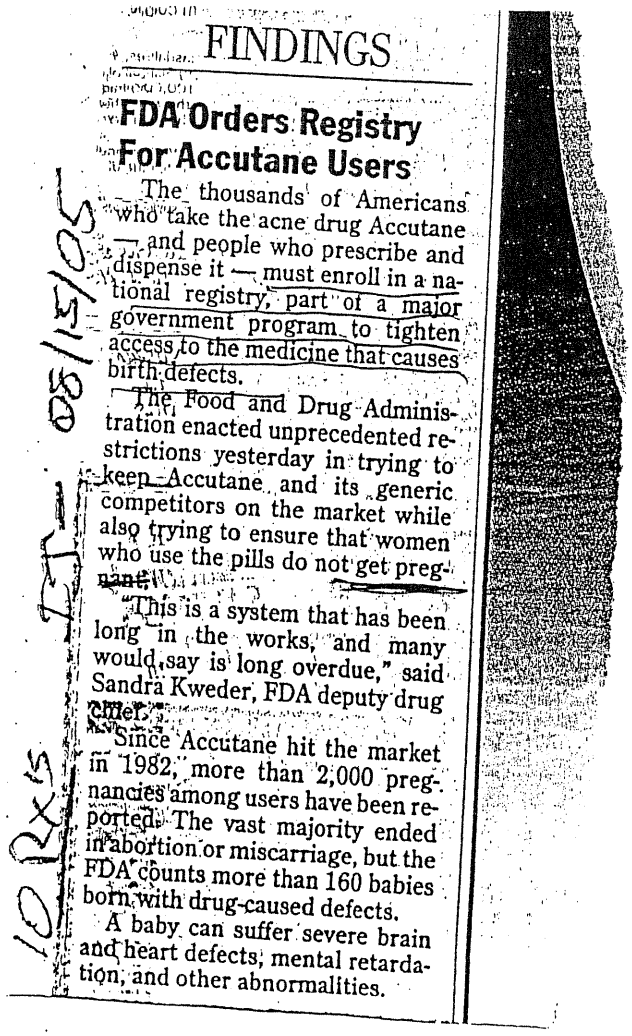
9. Inadequate Testing of Drugs in Older Adults Before Approval: Although older adults use a disproportionate share of prescription drugs, few of these drugs are adequately tested in older adults before being approved by the FDA.

Dr. Peter Lamy of the University of Maryland School of Pharmacy has stated, "We test drugs in young people for three months; we give them to old people for 15 years." The FDA is slowly remedying this serious problem by requiring that the people on whom a drug is tested be representative of those who will use the drug if it is approved. Nonetheless, most drugs on the market today, which are heavily used by older adults, were not adequately tested in this age group.

In summary, there are significant differences between younger and older patients, often not realized by doctors or patients. Increasing awareness of these differences will result in the prescription of far fewer drugs to older adults, and those that are prescribed will be given at lower doses in most instances.



FINDINGS

FDA Orders Registry For Accutane Users

The thousands of Americans who take the acne drug Accutane — and people who prescribe and dispense it — must enroll in a national registry, part of a major government program to tighten access to the medicine that causes birth defects.

The Food and Drug Administration enacted unprecedented restrictions yesterday in trying to keep Accutane and its generic competitors on the market while also trying to ensure that women who use the pills do not get pregnant.

"This is a system that has been long in the works, and many would say is long overdue," said Sandra Kweder, FDA deputy drug chief.

Since Accutane hit the market in 1982, more than 2,000 pregnancies among users have been reported. The vast majority ended in abortion or miscarriage, but the FDA counts more than 160 babies born with drug-caused defects.

A baby can suffer severe brain and heart defects, mental retardation, and other abnormalities.

NOTE!! TIGHTEN Access Birth Defects

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DRUG-INDUCED DISEASES

How Extensive Is the Problem of Specific Adverse Drug Reactions?

Each year, more than 9.6 million adverse drug reactions occur in older Americans. The referenced study found that 37% of these adverse reactions were not reported to the doctor, presumably because patients did not realize the reactions were due to the drug. This is not too surprising considering that most doctors admitted they did not explain possible adverse effects to their patients.[1]

The following national estimates are based on well-conducted studies, mainly in the United States:

• *Each year, in hospitals alone, there are 28,000 cases of life-threatening heart toxicity from adverse reactions to digoxin,* the most commonly used form of digitalis in older adults.[2] Since as many as 40% or more of these people are using this drug unnecessarily (see discussion on p. 144), many of these injuries are preventable.

• *Each year 41,000 older adults are hospitalized—and 3,300 of these die from ulcers caused by NSAIDs* (nonsteroidal anti-inflammatory drugs, usually for treatment of arthritis).[3] Thousands of younger adults are hospitalized. (For a list of drugs that can cause gastrointestinal bleeding, see p. 37.)

• *At least 16,000 injuries from auto crashes each year involving older drivers are attributable to the use of psychoactive drugs,* specifically benzodiazepines and tricyclic antidepressants.[4] Psychoactive drugs are those that affect the mind or behavior. (For a list of drugs that can cause auto crashes, see p. 34.)

• *Each year 32,000 older adults suffer from hip fractures—contributing to more than 1,500 deaths—attributable to drug-induced falls.*[5,6] In one study, the main categories of drugs responsible for the falls leading to hip fractures were sleeping pills and minor tranquilizers (30%), antipsychotic drugs (52%), and antidepressants (17%). All of these categories of drugs are often prescribed unnecessarily, especially in older adults. (See section on minor tranquilizers and sleeping pills, antipsychotic drugs, and antidepressants, p. 166.) The in-hospital death rate for hip fractures in older adults is 4.9%.[7] Multiplying this times the 32,000 hip fractures a year in older adults attributable to drug-induced falls, 1,568 older adults die each year from adverse drug reactions that cause hip fractures. (For a list of drugs that can cause hip fractures because of drug-induced falls, see p. 33.)

• *Approximately 163,000 older Americans suffer from serious mental impairment (memory loss, dementia) either caused or worsened by drugs.*[8,9] In a study in the state of Washington, in 46% of the patients with drug-induced mental impairment, the problem was caused by minor tranquilizers or sleeping pills; in 14%, by high blood pressure drugs; and in 11%, by antipsychotic drugs. (For a list of drugs that can cause or worsen dementia, see p. 28.)

• *Two million older Americans are addicted or at risk of addiction to minor tran-*

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Drugs That Can Cause Falls/Hip Fractures (continued)

BRAND NAME	GENERIC NAME
Antipsychotics	
ABILIFY	aripiprazole
GEODON	ziprasidone
COMPAZINE	prochlorperazine
HALDOL	haloperidol
MELLARIL	thioridazine
NAVANE	thiothixene
PROLIXIN	fluphenazine
RISPERDAL	risperidone
STELAZINE	trifluoperazine
THORAZINE	chlorpromazine
TRIAVIL	amitriptyline/perphenazine
ZYPREXA	olanzapine
Barbiturates	
BUTISOL	butabarbital
LUMINAL, SOLFOTON	phenobarbital
NEMBUTAL	pentobarbital
Tranquilizers or sleeping pills	
AMBIEN	zolpidem
ATARAX, VISTARIL	hydroxyzine
ATIVAN	lorazepam
BUSPAR	buspirone
CENTRAX	prazepam
DALMANE	flurazepam
DORIDEN	glutethimide
HALCION	triazolam
LIBRIUM	chlordiazepoxide
MILTOWN, EQUANIL	meprobamate
NOCTEC	chloral hydrate
NOLUDAR	methyprylon
PLACIDYL	ethchlorvynol
RESTORIL	temazepam
SERAX	oxazepam
SONATA	zaleplon
TRANXENE	clorazepate
VALIUM	diazepam
XANAX	alprazolam
Neurological drugs	
DILANTIN	phenytoin
KLONOPIN	clonazepam
LUMINAL, SOLFOTON	phenobarbital
TEGRETOL	carbamazepine
Other drugs	
ZYBAN	bupropion

Drugs That Can Cause Automobile Accid

BRAND NAME	GENERIC NAI
Mind-affecting drugs	
Antidepressants	
ANAFRANIL	clomipram
ASENDIN	amoxapine
AVENTYL, PAMELOR	nortriptylin
CELEXA	citalopram
ELAVIL	amitriptylir
LEXAPRO	escitalopra
LIMBITROL	amitriptylir chlordia
LUDIOMIL	maprotilin
LUVOX	fluvoxamir
NORPRAMIN	desiprami
PAXIL	paroxetin
PROZAC, SARAFEM	fluoxetine
SINEQUAN	doxepin
SURMONTIL	trimipram
TOFRANIL	imiprami
TRIAVIL	amitriptyl perphe
VIVACTIL	protriptyl
ZOLOFT	sertraline
Tranquilizers and sleeping pills	
AMBIEN	zolpidem
ATIVAN	lorazepar
CENTRAX	prazepar
LIBRIUM	chlordiaz
PAXIPAM	halazepa
SERAX	oxazepar
TRANXENE	clorazep
VALIUM	diazepar
XANAX	alprazol
SONATA	zaleplon

Drugs That Can Cause Sexual D

BRAND NAME	GENERIC
Antibiotics and other anti-infective ag	
NIZORAL	ketocon
TEGISON	etretina
Anticholinergics	
BANTHINE	methan
BENTYL	dicyclor
CANTIL	mepenz
DARBID	isoprop
DITROPAN	oxybut
HOMAPIN	homatr
PAMINE	methsc
PATHILON	tridihex
PRO-BANTHINE	propan

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Subj: **medguides**
Date: 10/17/2005 12:07:53 PM Pacific Daylight Time
From: lsasich@lecom.edu
To: PPSI@aol.com
Sent from the Internet (Details)

Under the regulations the dispensing pharmacist has specific responsibility for distributing Medication Guides to patients:

- Each authorized dispenser of a prescription drug product for which a Medication Guide is required under this part shall, when the product is dispensed to a patient (or to a patient's agent), provide a Medication Guide directly to each patient (or to the patient's agent) unless an exemption applies under 208.26.

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Black Box Warnings!

Kiosks?

ZOLOFT®
(sertraline hydrochloride)
Tablets and Oral Concentrate

Suicidality in Children and Adolescents

Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of ZOLOFT or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. ZOLOFT is not approved for use in pediatric patients except for patients with obsessive compulsive disorder (OCD). (See WARNINGS and PRECAUTIONS: Pediatric Use.)

Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials.

WHO SHOULD NOT TAKE ORAL CONTRACEPTIVES

Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives are strongly advised not to smoke.

EXOGENOUS FACTORS:
Potential drug interactions with warfarin sodium are listed below by drug class and by specific drugs.

Classes of Drugs:

5-lipoxygenase Inhibitor
Adrenergic Stimulants, Central
Alcohol Abuse Reduction Preparations
Analgesics
Anesthetics, Inhalation
Antiandrogen
Antiarrhythmics†
Antibiotics†
Aminoglycosides (oral)
Cephalosporins, parenteral
Macrolides
Miscellaneous
Penicillins, intravenous, high dose
Quinolones (fluoroquinolones)
Sulfonamides, long acting
Tetracyclines
Anticoagulants
Anticonvulsants†
Antidepressants†
Antimalarial Agents
Antineoplastics†
Antiparasitic/Antimicrobials
Antiplatelet Drugs/Effects
Antithyroid Drugs†
Beta-Adrenergic Blocker
Cholelithotlytic Agents
Diabetes Agents, Oral
Diuretics†
Fungal Medications, Intravaginal, Systemic†
Gastric Acidity and Peptic Ulcer Agents†
Gastrointestinal Prokinetic Agents
Ulcerative Colitis Agents
Gout Treatment Agents
Hemorrheologic Agents
Hepatotoxic Drugs
Hyperglycemic Agents
Hypertensive Emergency Agents
Hypnotics†
Hypolipidemics†
Bile Acid-Binding Resins†
Fibric Acid Derivatives
HMG-CoA Reductase Inhibitors†
Leukotriene Receptor Antagonist
Monoamine Oxidase Inhibitors
Narcotics, prolonged
Nonsteroidal Anti-Inflammatory Agents
Psychostimulants
Pyrazolones
Salicylates
Selective Serotonin Reuptake Inhibitors
Steroids, Adrenocortical†
Steroids, Anabolic (17-Alkyl Testosterone Derivatives)
Thrombolytics
Thyroid Drugs
Tuberculosis Agents†
Uricosuric Agents
Vaccines
Vitamins†

Specific Drugs Reported

acetaminophen
alcohol†
allopurinol
aminosalicylic acid
amiodarone HCl
aspirin
atorvastatin†
azithromycin
capecitabine
cefamandole
cefazolin
cefoperazone
cefotetan
cefoxitin
ceftriaxone
celecoxib
cerivastatin
chenodiol
chloramphenicol
chloral hydrate†
chlorpropamide
cholestyramine†
cimetidine
ciprofloxacin
cisapride
clarithromycin
clofibrate
cyclophosphamide†
danazol
dextran
dextrothyroxine
diazoxide
diclofenac
dicumarol
diflunisal
disulfiram
doxycycline
erythromycin
ethacrynic acid
fenofibrate
fenoprofen
fluconazole
fluorouracil
fluoxetine
flutamide
fluvastatin
fluvoxamine
gemfibrozil
glucagon
halothane
heparin
ibuprofen
ifosfamide
indomethacin
influenza virus vaccine
itraconazole
ketoprofen
ketorolac
levamisole
levofloxacin
levothyroxine
liothyronine
lovastatin
mefenamic acid
methimazole†
methyldopa
methylphenidate
methylsalicylate ointment (topical)
metronidazole
miconazole, intravaginal, systemic
morcizine hydrochloride†
nalidixic acid
naproxen
neomycin
norfloxacin
ofloxacin
olsalazine
omeprazole
oxaprozin
oxymetholone
paroxetine
penicillin G, intravenous
pentoxifylline
phenylbutazone
phenytoin†
piperacillin
piroxicam
pravastatin†
prednisone†
propafenone
propoxyphene
propranolol
propylthiouracil†
quinidine
quinine
ranitidine†
rofecoxib
sertraline
simvastatin
stanozolol
streptokinase
sulfamethizole
sulfamethoxazole
sulfinpyrazone
sulfisoxazole
sulindac
tamoxifen
tetracycline
thyroid
ticarcillin
ticlopidine
tissue plasminogen activator (t-PA)
tolbutamide
tramadol
trimethoprim/sulfamethoxazole
urokinase
valproate
vitamin E
warfarin overdose
zafirlukast
zileuton

also: other medications affecting blood elements which may modify hemostasis
dietary deficiencies
prolonged hot weather
unreliable PT/INR determinations

†Increased and decreased PT/INR responses have been reported.

Warfarin Sodium Tablets, USP

ZYPREXA®
Olanzapine Tablets

ZYPREXA® ZYDIS®
Olanzapine Orally Disintegrating Tablets

ZYPREXA® IntraMuscular
Olanzapine for Injection

WARNING

Increased Mortality in Elderly Patients with Dementia-Related Psychosis — Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Analyses of seventeen placebo-controlled trials (modal duration of 10 weeks) in these patients revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times that seen in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. ZYPREXA (olanzapine) is not approved for the treatment of patients with dementia-related psychosis (*see* WARNINGS).

Exhibit 6

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Useful drug information: 20 years and still waiting

Are patients getting sound written drug information with their new prescriptions? This issue has been at the center of a contentious debate for more than 20 years. The divisions have been along ideological lines—with pharmacists and their associations favoring a "marketplace for information" and consumers preferring a government-regulated program with quality standards and oversight.

The issue dates back to 1979, when the Food & Drug Administration proposed the first plan. It was killed in the early days of the Reagan Administration. In 1982, the National Council on Patient Information & Education (NCPIE) was formed, pledging to meet patients' information needs.

In 1995, the FDA proposed the Medication Guide rule. The same ideological forces that divided the FDA's 1979 plan greeted this proposal. A compromise was struck over the Medication Guide rule with the passage of Public Law 104-180 in 1996. This law called for the FDA to assess the effectiveness of current private-sector approaches to providing patients with drug information. If 75% of patients receiving new Rxs did not receive useful written information by the year 2000, the Department of Health & Human Services would be required to explore other initiatives. The HHS Secretary accepted the "Action Plan," as it was known, on Jan. 13, 1997. The Action Plan stated that drug leaflets to patients should be accurate, unbiased, sufficiently comprehensive, understandable, timely, and useful.

Next, the FDA granted a contract to the University of Wisconsin School of Pharmacy to conduct a national assessment of patient information leaflets. In June 2002, the FDA released the results of this assessment, which covered about 1,300 leaflets distributed nationally by pharmacists for atenolol, atorvastatin, glyburide, and nitroglycerin. The survey found that while 89% of patients received some written information, the information was only about 50% useful.

To Public Citizen, the concept that drug information can be 50% useful is unfathomable. Drug information that contains only half of what it should is misleading, and misleading drug information is potentially dangerous.

Based on the survey results, FDA concluded that progress has been made in meeting the goals set under the law. The agency said it would continue to work with private sector partners to improve the usefulness of patient information and meet the goal for the year 2006, which calls for 95% of patients obtaining new prescriptions to receive useful written drug information at the time of dispensing.

by Larry Sasich, Pharm.D.

Following the FDA's decision to delay action until 2006, Public Citizen's Health Research Group filed suit against the agency this past February, challenging the FDA's failure to seek public comment as required by the law. Negotiations began almost immediately, and the suit was settled in April. In the settlement, the FDA agreed to hold a public meeting this month and to open a docket to seek public comment. It is expected that some at this meeting will raise the issue of pharmacist counseling and oral information provided by health professionals.

Consumer groups are strongly supportive of verbal interactions between healthcare professionals and consumers, but given the limited amount of drug information that can be communicated to and retained by a consumer in this type of interaction, we continue to believe that FDA-approved written information provides patients with the best opportunity to avoid preventable adverse drug reactions. An August 1997 Office of Inspector General report found that enforcement of patient counseling laws by state pharmacy boards has been minimal, underscoring the need for mandatory distribution of FDA-approved written drug information.

Several professional trade organizations, including some representing pharmacy, have consistently supported the distribution of high-quality drug information for consumers. However, these same organizations also oppose FDA oversight of quality guidelines such as those contained in the Action Plan. Claiming support while opposing regulatory oversight is disingenuous and does nothing for the image of pharmacy as a health profession. The results of the University of Wisconsin survey clearly show the poor quality of drug information that consumers can expect without active FDA oversight of quality guidelines.

With the settlement of the Public Citizen lawsuit, patient information leaflets will once again come up for public debate. Pharmacy could cultivate smarter patients by remembering that voluntary programs have failed for 20 years and by supporting the only viable alternative available—an FDA-regulated program.

THE AUTHOR is a research analyst for Health Research Group, a division of the consumer advocacy organization Public Citizen.

Exhibit 7

Statistics on Consumers' Mixing Prescription Medicines with Over-the-Counter Drugs and Herbals

There are approximately 107,000 deaths each year due to the consumers' mixing of prescriptions medicines with OTCs/herbals--study done by Lucien Leppe, M.D., Harvard's School of Public Health.

These deaths are equivalent to people dying from crashes of three 747 airplanes each year. The American public never hears about these 107,000 deaths.

Adverse medication reactions to drugs cause hospitalizations of 1.5 million Americans each year - study done by Sidney Wolfe, M.D., Public Citizen, Washington, D.C.

28% of all emergency room visits are medication related including a large proportion due to the mixing of medicines.

Of these, 70% were preventable if the pharmacist adhered to the California Board of Pharmacy's rules and regulations regarding pharmacists' consulting with patients.

Research has shown that almost one out of four older adults living at home--6.6 million people a year--were prescribed a "potentially inappropriate" drug or drugs, placing them at risk of such adverse drug effects as mental impairment and sedation.

Seniors (over sixty-five) are 12% of the population but take 42% of prescription medicines.

Kiosks will take away all refills--approximately 50% of prescriptions--and place them in an ATM machine without a pharmacist's supervision and consultation.

In the Vioxx issue, which was settled last week for $260 million, over 20 million refill prescriptions for Vioxx were dispensed. If these were dispensed from a kiosk, how would pharmacists ever know if the patient was experiencing side effects to report to FDA?

Patients want to be able to consult a pharmacist on their prescription medicines. The California Board of Pharmacy's three consumer advocates all voted in consumer testimony against putting medications in a kiosk. These consumer advocates were out-voted by the Board's industry people from Longs, Safeway, and Walgreens. Industry and big business want kiosks to save money and increase profits, never minding about public health and safety.

Exhibit 8 (19)

Last year the California Board of Pharmacy through its three consumer advocates forced the Board to put out a "Special Notice to Consumers" stating: Before taking any prescription medicine, talk to your pharmacist. Be sure you know the following five points:

1. What's the name of the medicine and what does it do?
2. How and when do I take it and for how long? What if I miss a dose?
3. What are the possible side effects? What should I do if they occur?
4. Will the new medicine work safely with other medicines and herbals?
5. What foods, drinks or activities should I avoid while taking this medicine?

"Ask Your Pharmacist" - If using a kiosk to dispense medications, how does a patient ask a kiosk any questions? Why bother to waste the taxpayer's money to send this sign to all California pharmacies if patients are now going to get their information from a kiosk? Why train pharmacists eight years to get a pharmacy degree with another year of internship to receive a pharmacy license for patients to get medicines from a kiosk? Does anyone care that 107,000 deaths are occurring each year?

Forty-five million seniors under Medicare will be going to the federal government under the new Medicare Modernization Act, January 1, 2006, (five months from now), to purchase their prescriptions under the new Medicare program. With 107,000 deaths yearly and three 747s crashing each day, PPSI, a nonprofit, consumer, pharmacy education, public health organization predicts that this figure will double if the kiosk lawsuit and the consumers' wishes are not heard.

PPSI suggests in the interest of consumer health that each consumer obtain FDA's brochure "My Medicines" to keep a diary on all their medications, over-the-counter drugs and herbals as the kiosk will not be able to speak personally to them about their medicines. If interested in receiving this brochure, please send a self-addressed, stamped (37 cents) envelope to PPSI, 101 Lucas Valley Road, Suite 210, San Rafael, California.

Also I suggest each consumer purchase Public Citizen's book "Worst Pill/Best Pill", a consumer's guide to avoiding drug induced deaths and illnesses, to inform each consumer which one of their "kiosk purchased drugs" is dangerous since there will be no consultation with a pharmacist.

PERSONAL JOURNAL.

THE WALL STREET JOURNAL.

Generic Fares Well in Big Psychiatry Study

Newer, Costlier Drugs Have Little Advantage for Schizophrenia; Comparative Data on Side Effects

By Leila Abboud

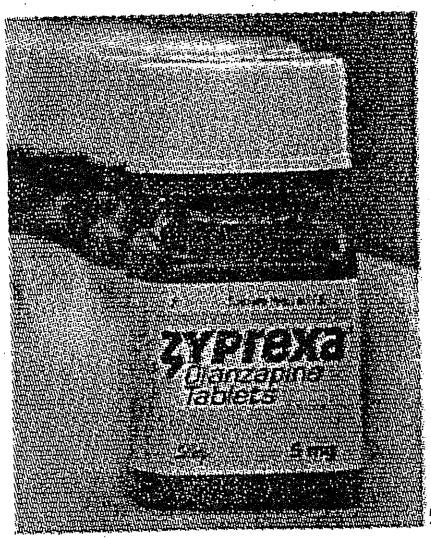
IN A SURPRISING finding, a government study comparing schizophrenia treatments found that an older generic medicine was as effective as all but one of the newer and more-expensive brandname drugs widely used to treat the devastating mental illness.

The $67 million federally funded study also exposed just how poorly current antipsychotic drugs really work: Nearly three-quarters of people treated stopped taking the medicine they had been given within 18 months, due to side effects or poor control of symptoms. The results, from the experience of 1,500 patients, are to be published in this week's New England Journal of Medicine.

The findings may have significant implications for how doctors treat the 3.2 million people in this country suffering from schizophrenia. The newer, costlier antipsychotics make up 90% of the market today. They are also used for bipolar disorder, and for severe cases of depression, kids with extreme behavioral problems, and dementia.

But psychiatrists have been prescribing these drugs with incomplete information about the benefits and risks of each drug. The studies that companies do to get drugs approved aren't designed to compare available treatments or shed light on the differences between similar drugs. When companies do compare their drugs to others, the studies have often been subject to criticism that they were designed in favor of a particular drug. So psychiatrists have had no head-to-head, impartial comparison to help them weigh treatments.

Now this trial, part of a six-year push by the National Institutes of Health to examine a range of psychiatric drugs, "provides a comprehensive set of data that were obtained independently of the pharmaceutical industry and in a scientifically rigorous way," says Jeffrey Lieberman, head of psychiatry at Columbia University and principal investigator on the trial, known as CATIE.



AP

Weight gain was a side effect with brand name **Zyprexa.**

Schizophrenia patients in the study were randomly assigned one of five drugs. The older antipsychotic perphenazine was found to be just as effective as three newer, so-called atypical antipsychotics: **Johnson & Johnson**'s Risperdal, **AstraZeneca** PLC's Seroquel and **Pfizer** Inc.'s Geodon, although each had slightly different side-effect profiles.

Eli Lilly & Co.'s Zyprexa was more effective than the other drugs. But the trial confirmed a concern that has emerged in recent years: The

Please Turn to Page D6, Column 1

Older Generic Drug Fares Well In Extensive Psychiatry Study

Continued From Page D1

new antipsychotics can cause extreme weight gain and lead to heart disease and diabetes, and Zyprexa causes more of these side effects than the other medicines. Zyprexa's manufacturer Eli Lilly had long argued that all the newer "atypical" antipsychotics caused these problems and the FDA eventually mandated a warning for the whole class.

It remains to be seen whether the findings will lead psychiatrists to change their prescribing habits. One thing to watch is whether public programs like Medicaid or private insurers use the findings to justify trying older generic medicines before the new ones.

Although the older drug, perphenazine, worked just as well as several of the newer drugs, some doctors may resist prescribing the older drugs because of long-held fears about side effects: In some people they cause involuntary movements, jerkiness and tremors. In the 1990s, drug makers came out with the new atypicals that supposedly caused fewer neurological side effects.

> Schizophrenia patients frequently must hunt for effective treatments.

Backed by huge marketing efforts, use of these newer antipsychotics has exploded, reaching $10.1 billion in U.S. sales last year, according to IMS Health. But some psychiatrists and researchers have been critical of how drug companies developed and promoted the medications.

Studies done by drug companies are too small and short-lived to pick up long-term safety problems, and they often exclude the sickest patients and people who have other diseases in addition to the illness being treated. Moreover, the companies' studies have generally compared the new drugs to high doses of Haldol, a potent older antipsychotic available as a generic that is known to cause relatively high rates of movement side effects.

Schizophrenia patients frequently must hunt for effective treatments. Lisa Halpern of Cambridge, Mass., tried a multitude of different drugs. Haldol gave her terrible tremors and restlessness. Clozaril from Novartis brought her out of the most severe period of her illness, but she gained nearly 30 pounds and often fell asleep. She's now on a cocktail of Seroquel and Bristol-Myers Squibb's newer drug Abilify, and the antidepressant Lexapro.

The new trial aimed to eliminate some of the guesswork in treatment. In the first stage of the study, if patients did well on the drug they were assigned, they stayed on it for the 18-month-long trial. But if the patient felt the drug wasn't working or experienced bad side effects, they were switched to another antipsychotic.

The primary measure of the drugs' effectiveness was how long patients stayed on them. The researchers chose this somewhat unusual trial design to reflect patients' and doctors' overall judgments on whether the benefits were worth any undesirable effects. Most psychiatric clinical trials measure a drug's effectiveness based on whether it relieves symptoms as measured by questionnaires and rating scales.

Patients on Zyprexa stayed on the drug for longest, for a median of 9.2 months. Patients on perphenazine, the older drug, stayed on for 5.6 months, Risperdal for 4.8 months, Seroquel for 4.6 months, and Geodon for 3.5 months. Nearly a quarter of people who stopped taking Seroquel, Risperdal, perphenazine and Geodon stopped because the drug wasn't working.

The study found no significant difference among the drugs in the incidence of neurological side effects like shaking. (However, the patients who discontinued perphenazine because of side effects were more likely to do so because of movement side effects.) The finding is notable because it undercuts the prevailing view shaped by drug-company marketing that the newer drugs cause fewer movement side effects. The researchers acknowledged that the finding may not represent the whole picture since the most serious of side effects can take years to emerge.

Patients on Zyprexa gained an average of two pounds per month. One-third of patients on Zyprexa gained more then 7% of their initial body weight compared with 16% of patients taking Seroquel, 14% taking Risperdal, 12% taking perphenazine, and 7% taking Geodon. Patients who discontinued Zyprexa because of side effects were more likely to do so because of weight gain.

The drug makers defended their drugs. Pfizer said Geodon, which has long had small market share because of nagging cardiac safety concerns, performed well and without weight gain or metabolic side effects. Lilly said the results proved that Zyprexa was superior to the other drugs, while Johnson & Johnson said the study didn't adequately reflect Risperdal's strengths because the doses given were too low. AstraZeneca said that Seroquel balanced efficacy and tolerability.

5 widely used drugs called unsafe

FDA officer says conflicts of interest compromise agency

By Marc Kaufman
WASHINGTON POST

WASHINGTON — A veteran Food and Drug Administration safety officer Thursday told a Senate hearing inquiring into the abrupt recall of the arthritis drug Vioxx that five other widely used drugs should be either withdrawn or sharply restricted because they have dangerous side effects.

Describing the agency that he works for as incapable of stopping dangerous drugs from coming to and staying on the market, David Graham, associate director of the Office of Drug Safety, told the senators that the FDA's role in reviewing and approving new drugs sometimes conflicted with its duty to address safety issues.

David Graham

Asked by Sen. Jeff Bingaman, D-N.M., to identify the five drugs, Graham hesitated and then listed them to the startled hearing room: the popular cholesterol-lowering drug Crestor, the weight-loss drug Meridia, the painkiller Bextra, the acne medication Accutane and the asthma medication Serevent.

Each poses different issues, Graham said in answer to questions from senators, but all require more aggressive action by the FDA.

AstraZeneca's Crestor, he said, poses risks of kidney failure and a rare muscle disease; Abbott Laboratories Inc.'s Meridia is of little use and has cardiovascular side effects; Roche's Accutane can cause birth defects if used by pregnant women; Pfizer's Bextra carries cardiovascular risks similar to those linked to Vioxx; and GlaxoSmithKline's Serevent increases the risk of dying of asthma. The makers of all five drugs later defended their products vigorously.

Dr. Steven Galson, acting director of the FDA's Center for Drug Evaluation and Research, said the agency already had taken steps to alert consumers to those drugs' safety concerns. That includes heightened warnings for Serevent; a tougher risk-management plan to ensure pregnant women don't use Accutane, and an upcoming advisory committee hearing regarding Bextra.

A 20-year veteran of the FDA, Graham has played a significant role in the withdrawal of nine drugs over the past decade, and his highly unusual attack on his own agency astonished many in the room. He called the FDA's handling of Merck & Co.'s Vioxx — which he said should have been pulled from the market years ago — the most distressing episode of all and a "profound regulatory failure."

"I would argue that the FDA as currently configured is incapable of protecting America against another Vioxx," Graham said in his scathing assessment. "The scientific standards (the FDA) applies to drug safety guarantee that unsafe and deadly drugs will remain on the U.S. market."

Citing estimates he said were based on the results of Merck's own clinical trials, Graham said between 88,000 and 139,000 Americans had probably had heart attacks or strokes as a result of taking Vioxx, and that 30 to 40 percent had probably died.

Graham also contended that FDA had an inherent conflict of interest that triggered "denial, rejection and heat" when safety questions emerged about products it had approved.

Graham's sentiments were endorsed at the hearing by two other drug safety experts, but they were disputed by a ranking FDA official as "not the FDA that I know."

Sandra Kweder, deputy director of the Office of New Drugs, said the agency was dedicated to protecting consumers and that drug safety was at the heart of its activities. She acknowledged, however, that "clearly, there's concern by the public and this committee that the system isn't working as well as it should, and we need to address that."

Asked about the five drugs that Graham identified as needing immediate action, Kweder said, "I don't have reason to believe that set of five drugs gives more reason for concern than any other set."

Graham's revelations and criticisms were the centerpiece of the hearing called by Sen. Charles Grassley, R-Iowa, chairman of the Senate Finance Committee and an increasingly sharp critic of the FDA. Following Graham's comments, Grassley pointedly warned agency officials against disciplining Graham in any way.

Grassley also suggested that an independent board of drug safety may be needed to ensure the safety of medications after FDA approval. An "awful lot of red flags" were raised before Vioxx was withdrawn, said Grassley, and the agency disdained, rather than listened to, its own reviewers.

Merck CEO Raymond Gilmartin came to the defense of the FDA and his company's actions in dealing with the issues around Vioxx, a heavily advertised and hugely profitable drug until it was abruptly recalled in September. He said the company had no scientific reason to withdraw the drug until it heard clear negative results reported by the safety monitoring committee of a clinical trial. At the time, Gilmartin said, his own wife was regularly taking the drug.

"Throughout Merck's history, it has been our rigorous adherence to scientific investigation, openness and integrity that has enabled us to bring new medicines to people who need them," Gilmartin said. "I am proud that we followed that same rigorous scientific process at every step of the way with Vioxx."

One of a class of painkillers known as COX-2 inhibitors that are widely used by arthritis sufferers, Vioxx was introduced in 1999. It was withdrawn after researchers halted a clinical trial because patients taking Vioxx were experiencing twice as many heart attacks and strokes as patients taking a placebo, but witnesses testified there had been suggestions of possible cardiovascular risks going back the mid-1990s.

Officials of the companies whose drugs were cited by Graham all said they were surprised by his testimony.

Carolyn Glynn, a spokeswoman for Roche, said it had long recognized that Accutane required special handling because of its known connection to birth defects.

AstraZeneca, the maker of Crestor, said in a statement that "to date, the FDA has not given the company any indication of a major concern regarding Crestor, and the comments today are inconsistent with past public statements from the FDA."

Abbott Laboratories issued a statement defending its weight-loss drug Meridia. "Obesity remains one of the leading health epidemics in the U.S., and Meridia is one of the few effective drugs that are currently available," it said.

GlaxoSmithKline stood by its asthma drug Serevent, saying it was "safe and effective when used appropriately."

Pfizer spokeswoman Susan Bro said its Cox-2 drug, Bextra, "has been found safe and effective when used as indicated." She noted that the company had already "committed to conducting further studies to confirm the longer-term cardiovascular safety profile."

The Associated Press contributed to this report.

Worrisome drugs?

Five drugs cited by a Food and Drug Administration official as the worst examples of those that remain on the market despite safety concerns:

- **Accutane**, a treatment for severe acne linked to birth defects and fetal death when used by pregnant women.
- **Bextra**, a painkiller found in a recent study to more than double the risk of heart attacks and strokes among patients with heart disease.
- **Crestor**, an anti-cholesterol drug linked to a muscle-destroying side effect and acute renal failure.
- **Meridia**, an obesity treatment linked to heart problems and, among pregnant women, stillbirths, miscarriages and birth defects.
- **Serevent**, an asthma medication that a study in England linked to increased deaths.

Source: Associated Press

NOTE - ENCLOSED

(26) Exhibit B

Pharmacists can be liable for drug risks / KIOSKS ??

By Curt Anderson, Associated Press Writer | June 3, 2005

MIAMI --A pharmacist can be held responsible for failing to warn about a medication's risks, even when filling a doctor's prescription, a Florida appeals court ruled.

The 4th District Court of Appeal said the duty to warn about using drugs repeatedly or in harmful combinations is based in the requirement that pharmacists have "general knowledge" of medicines they dispense and the risks they present.

The ruling this week lets Robert Powers pursue claims of negligence against two pharmacies -- Your Druggist and The Medicine Shoppe -- that filled his wife Gail's prescriptions for neck and back pain. She died of an overdose in October 2002.

The pharmacies said they plan to appeal.

Powers' attorney Peter Herman said the ruling was important for consumers because "a pharmacist is probably going to be in the best position to raise a red flag" about potentially harmful drugs.

Gail Powers, a 46-year-old waitress, had been taking six drugs, including painkillers OxyContin and Percocet and the anti-anxiety drug diazepam. These drugs can be harmful if taken together and some are highly addictive with long-term use, according to the Food and Drug Administration.

The negligence claims Robert Powers brought against the pharmacies had been dismissed by a trial judge, who said that under Florida law druggists are not liable if they are filling a doctor's legal prescriptions.

Wednesday's appeals court ruling reversed that decision while making no decision on the merits of Powers' claims.

"A strong policy basis already exists supporting a pharmacist's duty to warn customers of the risks inherent in filling repeated and unreasonable prescriptions with potentially fatal consequences," Judge Mark E. Polen wrote for the court.

On the Net:

Appeals court: http://www.4dca.org ■

Exhibit 9

Dianne E. Tobias, Pharm. D.
TOBIAS CONSULTING SERVICES

Carmen Catizone, MS, RPh, DPh
Executive Director/Secretary
NABP Foundation
700 Busse Highway
Park Ridge, IL 60068

June 1, 2004

Dear Carmen;

Enclosed please find our report for the Medication Error Analysis Proposal which was funded by the Foundation. As stated in the report and several emails, our original goals were not able to be realized because of some restrictions to data, but we still feel there is value in the effort and results.

We are seriously considering presenting the data at a national meeting in the Fall. Should you want the data presented at a NABP meeting, let me know.

Thank you again for your support of this project.

Sincerely,

Dianne Tobias, Pharm.D., CGP
Mark Sey, Pharm., CGP

CC: Patricia Harris

9/12/05
Fred,
This is the study you requested
Patty

Exhibit 10

P.O. Box 1407 • Davis, California, 95617
/759-9877 • 530/759-0377 Fax • detobias@aol.com

Table 3

Medication Errors from Citation / Fine Data Reports 1999-November 2003

Medication Error Category	Number	Percent of Total Citations
Wrong Drug	88	45.6%
Wrong Strength	44	22.8%
Wrong Instructions	21	10.9%
Wrong Patient	12	6.2%
Wrong Medication Quantity	8	4.1%
Other Labeling Error	10	5.2%
Compounding/Preparation Error	7	3.6%
Refill Errors (frequency, timeliness)	5	2.5%
Other (not listed)	10	5.2%
Total # Citations for errors (may have more than one category listed)	193	

U.S. Food and Drug Administration

FDA News

Department of Health and Human Services

FOR IMMEDIATE RELEASE
P02-52
December 9, 2002

Media Inquiries: 301-827-6242
Consumer Inquiries: 888-INFO-FDA

FDA STRENGTHENS CONTROLS, ISSUES CONSUMER ALERT ON IMPORTING CERTAIN PRESCRIPTION DRUGS

As part of its ongoing efforts to reduce preventable adverse events from the products it regulates, the Food and Drug Administration (FDA) today announced that it is strengthening the controls designed to protect patients by restricting imports of certain prescription drugs that can be used safely only with specified controls in place.

FDA's action involves adding the drugs to an existing FDA Import Alert, which alerts FDA field personnel to the possible importation of these drugs, provides guidance as to their detention and refusal of admission into the United States, and also advises United States Customs personnel to refer any attempted importation to the local FDA field office.

The drugs added to the Import Alert are as follows:

- Accutane (isotretinoin) - indicated for the treatment of severe recalcitrant nodular acne
- Actiq (fentanyl citrate) - indicated for the management of severe cancer pain in patients who are tolerant to opioid therapy
- Clozaril (clozapine) - indicated for the management of severe schizophrenia in patients who fail to respond to standard drug treatments for schizophrenia
- Lotronex (alosetron hydrochloride) - indicated for the treatment of severe irritable bowel syndrome in women
- Mifiprex (mifepristone or RU-486) - indicated for the medical termination of early intrauterine pregnancy
- Thalomid (thalidomide) - indicated for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum
- Tikosyn (dofetilide) - indicated for the maintenance of normal sinus rhythm in patients with certain cardiac arrhythmias
- Tracleer (bosentan)- indicated for the treatment of severe pulmonary arterial hypertension
- Trovan (trovafloxacin mesylate or alatrofloxacin mesylate injection) - an antibiotic administered in in-patient health care settings for the treatment of severe, life-threatening infections
- Xyrem (sodium oxybate)- indicated for the treatment of cataplexy in patients with narcolepsy

In a related action, FDA today alerted consumers not to buy these drugs over the internet,

Exhibit 11 (24)

... your continued support and interest in PPSI

because drugs obtained via websites usually are not accompanied by these safety controls. FDA is concerned about the safety risks posed by use of any of these products without the specified controls in place.

The revised Import Alert and the consumer advisory are available online at http://www.fda.gov/ora/fiars/ora_import_ia6641.html and http://www.fda.gov/oc/buyonline/consumeralert120902.html respectively.

Although these drugs have important benefits for many patients, they have serious known risks and so are available in the U.S. only under specially created safety controls. These safety controls are bypassed when these drugs are purchased from foreign sources, placing patients who use these imported drugs at higher risk. Therefore, because of this higher risk to patients, FDA took action to further curtail the products' availability from foreign sources. The drugs purchased from foreign sources are generally not FDA-approved.

Controls on these prescription drugs include limiting their distribution to specific facilities (such as hospitals); limiting their distribution to physicians with special training or expertise; or requiring certain medical procedures (such as pregnancy testing or blood testing) with their use.

Commissioner of Food and Drugs Mark B. McClellan, M.D., has set as a major FDA priority the reduction of
preventable adverse events. "The FDA is committed to taking action, through educational activities and other means where necessary, to improve patient safety," said Dr. McClellan. "Use of these FDA-approved products without adequate controls or monitoring, and using versions of these products not approved by FDA, increases the risk of serious adverse events for patients who might otherwise benefit from the drugs' use."

According to a 1999 report by the Institute of Medicine, medical errors in hospitals alone cause annually 40,000-98,000 deaths. The IOM has estimated that preventable adverse events cost the United States economy $17 billion a year.

Detailed information for consumers and patients who would like to learn more about how to buy prescription drugs safely may be found in FDA's guide, "Buying prescription Medicines Online: A Consumer Safety Guide," available online at http://www.fda.gov/cder/drug/consumer/buyonline/guide.htm

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 26 2005

Frederick S. Mayer, R. Ph., M.P.H.
President/CEO
Pharmacists Planning Services, Inc.
101 Lucas Valley Road, Suite 210
San Rafael, CA 94903

Re: Docket No. 2000P-1671/CP1

Dear Mr. Mayer:

This letter responds to the citizen petition submitted by Pharmacists Planning Services, Inc., requesting that the Food and Drug Administration (FDA) issue a patient medication guide (MedGuide) for distribution with all prescription non-steroidal anti-inflammatory drugs (NSAIDs), including the so-called "COX-2 selective" drugs, to provide patients appropriate warning and risk information relating to gastrointestinal (GI) bleeding associated with the use of these drugs. For the reasons described below, your petition is granted.

On April 7, 2005, FDA issued a Public Health Advisory (PHA) in which it announced several actions relating to both COX-2 selective and non-selective NSAIDs, including plans to issue a MedGuide for patients addressing the cardiovascular and GI risks associated with the use of prescription drugs in this class. The MedGuide will inform patients of the need to discuss with their doctor the risks and benefits of using prescription NSAIDs, and the importance of using the lowest effective dose for the shortest duration possible if treatment with an NSAID is warranted for an individual patient.

We have attached the PHA and related documents issued by FDA on April 7, and our memorandum entitled "Analysis and recommendations for Agency action regarding non-steroidal anti-inflammatory drugs and cardiovascular risk." These documents detail the scientific and regulatory findings upon which FDA based these actions.

Accordingly, your petition is granted. Thank you for your continuing interest in promoting public awareness of safe use of medications.

Sincerely,

Steven K. Galson, M.D., M.P.H.
Acting Director
Center for Drug Evaluation and Research

Attachments

Exhibit 14

27

PHARMACY PRACTICE NEWS

Pharmacist's News Source Volume 32 • Number 9 • September 2005

Day Surgery Patients Found At Risk for Medication Errors

HONOLULU—A preliminary study of day-surgery patients revealed a high rate of potentially harmful discharge prescription errors.

More than half of the prescriptions examined were found to have errors, based on criteria set by the Institute for Safe Medication Practices (ISMP), reported Tracey L. Stierer, MD, Director of the Outpatient Surgical Center, Johns Hopkins Medical Institutions, Baltimore.

According to Dr. Stierer, this is the first study to examine medication errors among day-surgery patients. "These patients

see Day Surgery Errors, page 28

Day Surgery Errors

continued from page 1

are particularly vulnerable, because once discharged, they are no longer under the surveillance of medical personnel," she told *Pharmacy Practice News*. "Children are particularly at risk, because they are frequently unable to verbalize that they are having a reaction."

The investigators examined prescriptions and discharge forms of surgical patients at a day surgery facility and conducted a preliminary analysis of the first 75 patients. Data were collected over seven days. Errors were classified as "dose errors," "missing information," or "patient identification errors."

Errors were classified as "potential adverse drug events" if the investigators determined that the error had the potential to injure the patient, Dr. Stierer reported at the 2005 annual meeting of the International Anesthesia Research Society. The clinical services being observed were not informed about the study. The anesthesiology service rewrote any prescriptions that contained any errors that would be considered potential adverse drug events.

In all, 75 patients (48 women) were studied. The ages ranged from 1.3 to 84 years, with an average of 38.5 years; average weight was 71.9 kg, Dr. Stierer noted. Analgesics were the most commonly pre-

Exhibit 15

WSJ.com THE WALL STREET JOURNAL. ONLINE

October 12, 2005

Generic Drugs Sampled Freely In Aetna Test

By SCOTT HENSLEY
Staff Reporter of THE WALL STREET JOURNAL
October 12, 2005; Page B1

Moving to trim drug spending, several insurers are paying to put ATM-style machines dispensing generic-drug samples in doctors' offices around the country.

Aetna Inc. this week plans to unveil a pilot program in which it wants to place the machines with physicians around Philadelphia, in advance of a possible national rollout. The test, if expanded, could represent the largest use of the ATM-generic strategy to date. Currently, the machines can be found in an estimated 100 physicians' offices from New Jersey to California, paid for by various insurers or insurer groups.

WALL STREET JOURNAL VIDEO

WSJ's Scott Hensley discusses[2] offering generic-drug samples in your doctor's office.

The generic-drug dispensers aim to provide a counterweight to the samples of branded drugs distributed freely by sales representatives working for pharmaceutical companies. Last year, doctors received more than one billion branded drug samples -- three for every person in the U.S. -- valued at nearly $16 billion, an 18% increase over 2003, according to data from IMS Health, Fairfield, Conn. Makers of low-priced generic drugs don't provide samples to doctors, except in rare cases, because of the expense and lack of sales forces.

The automated dispensers of generics offer some advantages over branded samples. Samples of brand-name drugs, for example, usually last only a week or so. The generic-drug machines usually dispense 30-day supplies of medication. To use one of the machines, a doctor would punch in a security code and receive a packet of medicine used for some of the most commonly treated conditions, such as high blood pressure, depression or diabetes. To make the machines easy to use and to encourage generic prescribing, Aetna and MedVantx want doctors to dispense appropriate generic samples to all patients, regardless of their insurance plan.

Doctors like drug samples because they help get sick patients started on a course of medicine right away and boost the likelihood they will see it through. And samples are an opportunity to test-drive a drug for a particular patient before the prescription is filled and paid for.

But every branded sample is probably a lost opportunity for a doctor to prescribe a cheaper generic. The tendency among doctors is to write prescriptions for the medicine samples they have

on hand.

The machines in the Aetna pilot will be installed and supplied with drugs by MedVantx, a closely held San Diego company. They stock as many as 20 different generic drugs used in treating nine categories of illness, including diabetes, high blood pressure, heartburn and depression.

Neither MedVantx nor Aetna, of Hartford, Conn., is offering payments or other inducements to doctors who agree to accept the machines in their practices. Richard Payne, an Encinitas, Calif., family physician, says, "Patients thank us if we can give them a drug that will cost them less." His six-physician group practice has been using the MedVantx system for two years. In addition to saving money, he says, the generic samples give him more confidence that his patients take the drugs he prescribes. "I know if I can give them their medicine free, they're going to take it," he says.

"We're saving patients money," says Jeff Taylor, director of pharmacy for Aetna. For common infections, the machines would provide a sample adequate to treat the condition -- meaning the patient's drug cost would be zero.

At present, about half the prescriptions Aetna processes nationwide are for generic medicines. Mr. Taylor says an increase of even a few percentage points would be a victory.

Aetna has tried the MedVantx machines in eight regions so far. The Philadelphia test will be the broadest and the most rigorously analyzed for its effects on prescribing patterns.

The challenge for Aetna and other insurers is to identify practices with enough of their own insured patients to justify the financial commitment of installing and stocking the machines. Eventually, MedVantx hopes networks of its machines sponsored by insurer groups will encourage generic prescribing.

Financial terms of the relationship between MedVantx and Aetna haven't been disclosed. MedVantx, not Aetna, owns the equipment and provides the packets inside. Aetna pays MedVantx for the drugs dispensed, plus a processing fee.

In the past two years, MedVantx machines installed at more than 100 doctors' offices have dispensed more than 111,000 samples, the company said.

Write to Scott Hensley at scott.hensley@wsj.com[3]

URL for this article:
http://online.wsj.com/article/SB112908675852366369.html

Hyperlinks in this Article:
(1) http://online.wsj.com/public/page/0,,8_0000-JszBw5yg_k5W7wdJLO7pBmEVeMBkqZwz-JfwzQ0CotakOMZwcNjC0VlnBmNmjRDng,00.html?mod=ARTICLE_VIDEO
(2) http://online.wsj.com/public/page/0,,8_0000-JszBw5yg_k5W7wdJLO7pBmEVeMBkqZwz-JfwzQ0CotakOMZwcNjC0VlnBmNmjRDng,00.html?mod=ARTICLE_VIDEO
(3) mailto:scott.hensley@wsj.com

Campaign for Patient Safety

"Don't just swallow it... ask first"

Campaign for Patient Safety (CPS)

Sunday, March 19, 2006; 2 p.m. - 4 p.m.
Hilton Hotel
333 O'Farrell Street
San Francisco, California

Chairperson

Lynn Rolston
CEO, California Pharmacists Association (CPhA)
Sacramento, California

Speakers

Michael Cohen, R.Ph., MS, DSc
Institute for Safe Medication Practices
Huntingdon Valley, Pennsylvania

Orriette "Cooky" Quandt, Pharm.D.
Pharmacy Compliance Manager
Longs Drug Stores
Walnut Creek, California

Thomas J. McGinnis, R.Ph.
Deputy Director, Food and Drug Administration (FDA)
Rockville, Maryland

Jackie Speier, Senator (invited)
Chairman, California Insurance Committee
Sacramento, California

Exhibit 17 (31)

pharmacists planning service, inc.
101 Lucas Valley Road, Suite 210 • San Rafael, California 94903
Tel: (415) 479-8628 • Fax: (415) 479-8608 • e-mail: ppsi@aol.com

September 20, 2005

Patty Harris, CEO
California State Board of Pharmacy
400 R Street
Sacramento, CA

Dear Ms. Harris:

PPSI, a 501 C (3) nonprofit public health, consumer, pharmacy education organization has concerns to be presented to the BOP's Licensing Committee chaired by David Fong, Pharm.D. at it's upcoming meeting: I am sorry that this information was not sent yesterday, but my computer crashed.

Our issues of concern are:

1. In the Medication Error Analysis Study from the Cite and Fine Committee of the California Board of Pharmacy sent by you to PPSI for the Campaign for Patient Safety (CPS) group, documented by Dr. Tobias and Mark Sey, it states that over 80% of the medication errors are: wrong drug (45.6%); wrong strength (22.8%); wrong instructions (10.9%); wrong patient (6.2%). Medication errors are due to these categories.

CPS proposes: that the License Committee look at these issues; institute e-scripts for all healthcare providers (this would put California in compliance with the Medicare Modernization Act MMA which mandates electronic prescribing, e-prescribing, to eliminate handwritten Rx's); have the ICD-9 codes listed on all Rx's which would take care of the 45.6% of the wrong drug in the wrong bottle; and increase the amount of consultation by pharmacists which would take care of the above problems. This is not being done at the present time.

2. PPSI's Citizen's Petition which was approved by FDA after waiting nine years (1998-2005) - FDA Docket No. 20000P-1671/CP1- in a letter dated July 26, 2005, FDA agreed to issue a patient medication guide (MedGuide) for distribution with all Rx's nonsteroidal, anti-inflammatory drugs (NSAIDs), including the so-called "Cox-2 selective" drugs, to provide patients appropriate warning and risk information relating to gastrointestinal (GI) bleeding associated with the use of these drugs.

Exhibit C (32)

Larry Sasich, Pharm.D., MPH, FASHP, PPSI's consumer advocate expert in the MedGuide field, from Public Citizen and Associate Professor at Lake Eire School of Pharmacy in Pennsylvania has documented the following:

"With respect to your e-mail of September 16, 2005 concerning the value of distributing patient safety information and Medication Guides stemming from the Entwistle et al. study appearing in the September 2005 issue of the Journal on Quality and Patient Safety. Patient safety as used in the context of the study refers to medical errors while Medication Guides are Food and Drug Administration (FDA) approved drug information written specifically for patients.

"These should be viewed as two distinctly separate issues:

1.) preventing medical errors; and
2.) avoiding preventable adverse drug reactions.

Estimates suggest that 7,000 patients may die per year from medical errors which the estimate is as high as 100, 000 per year from preventable adverse drug reactions. The FDA has been involved in setting standards for written drug information and conducting research on the quality of information being given by pharmacists and physicians for over 25 years. Extensive regulations exist regarding the content of Medication Guides and the public did have an opportunity for input into the rules.Unfortunately, only 75 drugs are currently required to be dispensed with Medication Guides. Many feel that the Medication Guide rule should be extended to all prescription drugs sold in the U.S."

Mandatory MedGuides for NSAIDs and SSRIs and anti-psychotics along with the 75 additional FDA MedGuides are not being distributed by pharmacists in California in violation of the FDA laws. PPSI would like the Licensing Committee of the California Board of Pharmacy to look into this violation ASAP and inquire why this is happening.

3. In the Medicare Modernization Act (MMA) Act of 2003, it specifically states that pharmacists should be performing one-on-one patient consultation and drug utilization review (DUR). This professional act needs to be increased to decrease prescription drug errors.

In five states (Kentucky, Louisiana, Arkansas, Nebraska and Tennessee) mailorder pharmacies and PBMs are required to have pharmacists and pharmacists-in-charge (PICs) who are licensed by their respective states in order to fill Rx's and ship into the five above mentioned states.

In compliance with MMA, PPSI respectfully requests that the California Board of Pharmacy Licensing Committee ask all PBM and mailorder firms, PDPs, etc. who ship Rx's into the State of California, have a California licensed pharmacist and pharmacist-in-charge (PIC) to be in compliance with the MMA Act of 2003. PPSI requests that these pharmacists initiate pro-active consultation to reduce the 80% error rate from the Board's study by Tobias/Sey. Pharmacists must also document any errors similar to the California BOP's quality assurance responsibilities.

Many, many thanks for presenting these issues to the Licensing Committee Chairman, David Fong, Pharm.D. at the Board of Pharmacy Licensing Committee meeting.

Sincerely,

Fred S. Mayer, R.Ph., MPH
President

ATMs not the answer for drug

LETTERS

DRUG TOPICS FEBRUARY 7 2005

The use of automated prescription vending machines, covered in your December issue, represents a way of decreasing the amount of staffing required to help customers in the retail setting. Perhaps this will help those customers who want an "express" in and out without having to stand in long lines at the pharmacy. But if there is a question about the medications patients are picking up, won't they have to get into that long line again?

There is still a need for someone to fill these machines and to verify that the medication put into the bag is correct. I see these machines not so much as a way to decrease the amount of staffing in the pharmacy as to create a new line for the customers.

Many patients still enjoy interaction with the pharmacy staff when they pick up their medication. This interaction allows the pharmacist and staff to explain that there has been a change in manufacturer, the color of the tablet may look different, the copay has increased, or the day supply has been reduced. It is to be hoped that these questions, and others, will be addressed when consumers pick up their medication from the machine. If not, the state board of pharmacy is neglecting its purpose to serve the consumer.

Whallen Fong
wha52@hotmail.com

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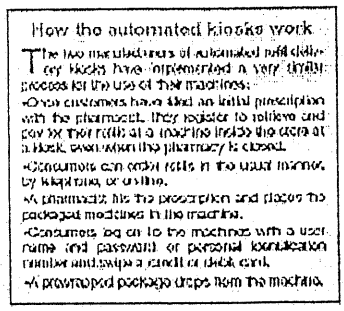
DRUG TOPICS

Will ATMs replace you?

Vending machines for medications may be an idea whose time has come, but they are creating a firestorm of controversy among pharmacists

Oct 10, 2005
By: Martin Sipkoff
Drug Topics


How the automated kiosks work

The two manufacturers of automated refill delivery kiosks have implemented a very similar process for the use of their machines:

- Once customers have filled an initial prescription with the pharmacist, they register to retrieve and pay for their refills at a machine inside the store or a kiosk, even when the pharmacy is closed.
- Consumers can order refills in the usual manner, by telephone, or online.
- A pharmacist fills the prescription and places the packaged medicines in the machine.
- Consumers log on to the machines with a username and password or personal identification number and swipe a credit or debit card.
- A prewrapped package drops from the machine.

How the automated kiosks work

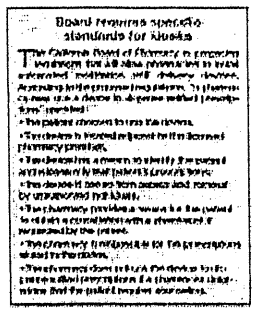
The beauty of any new technology is in the eye of the beholder. Advocates of the medication delivery kiosks that are sprouting up across the country believe the ATM-like machines free pharmacists to spend more time with customers, and free customers to pick up refills anytime day or night. Opponents say the contraptions are dangerous, replacing invaluable human contact with impersonal mechanization.

"They are really no different than the pickup windows at drugstores," said Bradley Dayton, R.Ph., director of pharmacy operations for Ahold USA, the parent company of supermarkets Giant Food, Stop & Shop, and Tops Markets. His company is placing an automated drug kiosk in a pilot project in a Reston, Va., Giant store by the end of the year. It may also place a machine in Maryland soon, pending approval by the Maryland Board of Pharmacy. "These machines are only delivery machines, only for refills. They are not dispensing machines," he said.

Ahold has contracted with Asteres Inc. in Del Mar, Calif., one of two companies manufacturing the kiosks. According to Asteres founder and chief business officer Linda Pinney, the machines offer a safe and convenient way for customers to pick up their refills. "That's what it is about, convenience," she said. "A lot of grocery stores are open all day and night, but the pharmacy closes at five or six. People have very different needs when it comes to their work and home life schedules. We address that problem in pharmacy, just as it has been addressed in banking and other services."

Longs Drugs Stores pharmacist Pawny Kelly, R.Ph., in Del Mar, said her customers love the kiosk Asteres placed at her Del Mar pharmacy last December. "Everybody does. It's convenient for them, convenient for us," she said. "No waiting in line, better control over when they can come in. Lots of customers ask for us to put the refill in the machine."

The Asteres machine is called ScriptCenter. The other manufacturer is Distributed Delivery Networks Corp. (ddn) in San Marcos, Calif. It calls its machine the Pharmaceutical Automated Product Machine, or APM. The cost of the ScriptCenters ranges from $65,000 to $95,000 each. The ddn APMs range from $45,000 to $60,000, and the company is planning to introduce a smaller-capacity version that would run about $39,000. Both machines hold hundreds of refills.

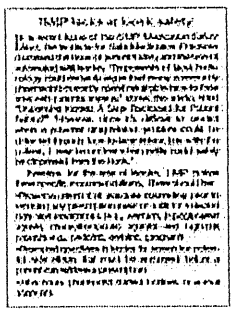

Board requires specific standards for kiosks

Proponents say kiosks safe

Pinney said that contrary to the concerns of critics, the machines are designed to encourage consultation. They have a screen that asks consumers whether they have questions about their medications. If so—and if the pharmacy is open, of course—the consumer can speak directly to the pharmacist. "We do not replace pharmacists," said Pinney. "We are pharmacy clerks, definitely not pharmacists."

Justin Hai, ddn's APM project manager, believes the kiosks actually are safer than "the usual manner of having a busy clerk reach for an order on a shelf to hand to a customer. The biggest threat to public safety at the pharmacy level comes from human error, not machine error. Our systems have multiple levels of verification and safeguards, including bar-code scanners and personal customer codes and passwords to make sure the correct medication goes to the correct person."

"Prescriptions going to consumers is like money going to consumers," Pinney said. "The margin for error is zero."


ISMP looks at kiosk safety

A different kind of kiosk is being marketed and installed in some drugstores. Those units allow customers to talk to pharmacists through video screens. Duane Reade in New York has contracted with New Edge Networks in Vancouver, Wash., to install what New Edge calls "self-help kiosks" that use a private and secure broadband network and a digital subscriber line to carry voice, data, and video without using the Internet. The self-help kiosks are available round-the-clock.

Each kiosk has a flatbed scanner, touch-screen monitor, phone line, and a Web camera allowing people to talk live with a pharmacist. Patients can receive free home delivery or make arrangements for pickup at any Duane Reade pharmacy. There are currently more than 60 self-service kiosks in company locations with 2,000 employees or more, in major medical and hospital facilities, at senior care centers, and at Duane Reade stores in the New York City metropolitan area. Duane Reade plans to double the number of kiosks every 12 months. And DrugMax, a specialty pharmacy and drug distribution company in Farmington, Conn., just signed an agreement with Duane Reade to market its products through the electronic kiosks.

Another company, MedVantx in San Diego, signed a contract with Blue Cross Blue Shield of North Dakota earlier this year to dispense generic drugs in doctors' offices by using devices very similar to the Asteres and ddn machines. Called the Generic Delivery Network, the pilot project has been launched in physician offices in Fargo and Grand Rapids. The Generic Delivery Network relies on machines that dispense samples of generic medications in nine therapeutic categories. The devices are also used by the New Jersey Blues.

Each doctor is assigned an identification number. "That number and the patient information [either through the patient registration system or by scanning] are entered. This gives the doctor access to the medications in the machine. Appropriate labels for the medication and for the medical record are printed after the medication's bar code is scanned to confirm that it matches the request," said John Rice, M.D., the plan's medical director.

Technologies may come together

These technologies may all merge at one point, say technology experts. It is all part of what they believe is an inevitable shift in service. The fact that self-service is encroaching into pharmacy should shock no one, these experts say: "It is not surprising that traditional retail point-of-sale has evolved beyond checkout," said Paula Rosenblum, director of retail research at the Aberdeen Group in Boston, in a report titled, "The Empowered Point of Service." "Adding self-service touch points throughout the store can help hold the line on payroll while improving customer convenience," she noted.

Asteres and ddn officials couldn't agree more. "This follows in the tradition of mail order and drive-up windows,"

said Pinney. In fact, part of the motivation for drugstore chains to install the machines may be a growing need to compete with mail order, which accounted for 14% of prescription drug sales last year, up from 10% in 1999, according to IMS Health Inc.

Officials of the two delivery kiosk companies say they are prepared to serve a potentially large and growing market. Their two machines are actually quite similar in design and capability. So similar, in fact, that Asteres filed a lawsuit last year against ddn, accusing the company of misappropriating trade secrets. The president of ddn, William Holmes, denies the accusation. A trial was scheduled for September.

The lawsuit apparently isn't slowing either company. In addition to California, boards of pharmacy in Connecticut, Delaware, Illinois, Maryland, Minnesota, New York, Virginia, and Wisconsin have either given permission for pilot installations or are expected to do so soon, according to the manufacturers. Boards in many other states are also expected to take up the issue. Several large drugstore chains, supermarkets, and discount stores—including Longs, Duane Reade, Safeway, Kmart, and Walgreens—are putting the machines in some of their locations. Some smaller regional outlets, such as a White Cross Drug Store in San Diego, are also installing the machines.

At this point, most of the installations are being called pilot projects by state boards and vendors. But with new customers announced by one or the other of the manufacturers almost monthly, it appears the technology is increasingly popular among chains and consumers. As of August, Longs officials said that 700 of its customers have signed up at three of its stores, representing about 10% of refills at those stores.

"There's always been a convenience problem of hours and staffing in community pharmacy," said Mary Ann Wagner, senior VP of pharmacy, policy and regulatory affairs for the National Association of Chain Drug Stores. "Our members tend to think these machines can be of value if they are monitored properly and if the right identification is required."

The machines are designed to work like the ubiquitous ATMs at banks: In order to receive their medication, consumers register with their drugstore and receive identifying information, such as a personal identification number. When they want to pick up their medication, they enter the PIN on a touch screen. Then they swipe a credit card to pay for the refill. As of now, there's no service fee. Labeled and bagged medication comes out a chute.

The kiosks are stocked by pharmacists during regular working hours, but they are designed to make refill pickup available 24 hours a day, seven days a week—an improvement on drive-up windows. They also help eliminate the long waiting lines that can plague drugstores customers. That's the good news, at least for consumers.

Pharmacists concerned over ADEs

The bad news, according to some pharmacists, is that the machines eliminate them from the actual delivery of a refill. "How can they possibly say these machines are safe?" asked Fred Mayer, president of Pharmacists Planning Service Inc. (PPSI), a nonprofit organization in San Rafael, Calif., that promotes consumer public health education and pharmaceutical information. "How can any machine be as safe as picking up your refill from a human being, talking to that person, who can check right there and then that you've received the medication you're supposed to receive, or warn you about anything you need to know?"

Mayer is concerned that the lack of pharmacist involvement in refill delivery could lead to an increase in adverse drug events (ADEs). "We already have 107,000 deaths a year from adverse drug reactions and interactions," he said. "Do we want more?" He also thinks customers, particularly seniors, could be robbed of their medications, depending on where the machines are located. And he's very worried that refills are just the beginning, and that it's simply a matter of time before the machines are used to fill first-time orders. He also believes machines simply aren't meant to store and dispense medications. Some drugs, like insulin, are time-sensitive, and others, such as the acne drug Accutane (isotretinoin, Hoffmann-La Roche) can pose serious health risks to women who are or are about to become pregnant.

There is support among pharmacists for Mayer's position. PharmacyOneSource, which posts industry news on its Web site (www.pharmacyonesource.com), conducted an informal opinion poll between Aug. 28 and Sept. 2 of pharmacists' reactions to the kiosks. The poll asked readers "How do you feel about the self-service prescription medication vending machines being installed in retail pharmacies across the country?"

Of 149 respondents, 101 (67.8%) were "strongly opposed" to the idea. Another 18 (12.1%) of respondents were "opposed." Only 20 (13.4%) either "strongly supported" or "supported" the idea. The rest were indifferent or had association's concerns will be addressed. "There is some inevitability to all this," he said. "But that's all the more reason to move forward carefully."

"other" opinions. In anonymous remarks attached to the poll, respondents said things like "With no more interaction than patients are getting at this point, wasn't something like this inevitable?" and "First for refills, then ????"

"Our members are worried about this kind of technology," said John Rector, general counsel for the National Community Pharmacists Association. "Medications aren't something like a CD or a book you order from Amazon.com. They are highly regulated products. Highly regulated transactions should always actively involve the physician, pharmacists, and the patient. There should be more patient-pharmacist interaction, not less. These vending machines put more distance between them, without any apparent remedy in place if there's a mistake."

"Pharmacist consultation isn't something that should happen just the first time you get your medication," said Mayer, pointing out that 58% of the prescriptions filled in this country are for refills. "Every time a person picks up a drug, he or she should have the opportunity to talk face-to-face with their pharmacist."

But NACDS' Wagner said that "as we understand it, the machines do not preclude conversation between pharmacist and patient. The machines are not dispensing drugs. They're only for delivery. But no pharmacists would ever want to be replaced by a machine, and we are watching this development closely."

Lawsuit against board

Mayer and his group are putting their money where their worries are. Their legal foundation, the Pharmacy Defense Fund, filed suit in December to stop the California Board of Pharmacy from waivers allowing the installation of the kiosks. The suit was filed soon after the California Board of Pharmacy approved waivers to pharmacies run by Longs Drug Stores and Safeway supermarkets allowing them to install the Asteres' ScriptCenter kiosks in a couple of their stores. It was dismissed in August on a jurisdictional technicality and refiled in a San Francisco court in September.

The Pharmacy Defense Fund makes two claims in its suit. First, the pharmacists assert that the board lacked the authority to approve the machines, primarily because several of the board members "were employed by pharmacy entities that had made, were planning to make, or may make application" for installation of the kiosks. Second, the plaintiffs claim the board failed to properly follow its own regulatory procedures in approving the waivers.

Notwithstanding the pending litigation, in August the board posted notice of a proposed permanent regulatory change that creates criteria for the proper use of the machines. A public meeting on the proposed regulation will be held on Oct. 25. "There is some misunderstanding among some pharmacists about these machines," said Patricia Harris, the board's executive director. "They are delivery machines, not dispensing machines, for refills only. So they are currently in compliance with state regulations. What we are doing is precisely defining how we want them used."

The board proposal contains several specific requirements, including limiting the kiosks' use to refills and requiring them to be placed in close proximity to a pharmacy. The regulation, as it is currently written, satisfies some of the concerns of the California Pharmacists Association, said John Cronin, senior VP and general counsel for the association, adding his initial reaction to the kiosks was pretty negative. "I was at the board meeting when the first waivers were granted," he said, "and my reaction was that this was the beginning of the slippery slope toward breaking the link between pharmacist and patient."

But further examination of the issue, and discussions with the vendors, led Cronin to believe there is a role for the kiosks—as long as an opportunity exists for consultation. The proposed regulation does not satisfy two continuing concerns, however. In an April letter to the California pharmacy board, Cronin asked that pharmacies using the kiosks be required to file a "pharmacy services plan" that would clearly demonstrate how it would provide for patient consultations once the machines were installed. In addition, "compliance with the plan would be monitored by periodic visits by board inspectors. Failure to comply with the proposed pharmacy services plan would be a basis for withdrawal of the waivers, or other action by the board."

"That kind of requirement, a clear outline of how the machines will be used and consultations encouraged, would go a long way toward the board's commitment to its mission of encouraging pharmaceutical care," said Cronin. He added that the board's current slogan is "Be Aware, Take Care—Talk to Your Pharmacist."

"There is a place for these machines," Cronin said. "We don't want to see technology suppressed, but we need to move cautiously." He said he plans to attend the board's October public meeting to see whether the association's concerns will be addressed. "There is some inevitability to all this," he said. "But that's all the more reason to move forward carefully."

THE AUTHOR is a healthcare writer based in Gettysburg, Pa.

Dietary Supplement Safety Committee (DSSC) Meeting

Thursday, October 20, 2005; 10 a.m. - 1:00 p.m.

UC - Berkeley

120 Morgan Hall

Berkeley Campus

Agenda

1. Welcome & Introductions - Ed Blonz

2. Ephedra Moves On - New Ephedra Sales - - - even in California
   Update from June, Ephedra Litigation Conference

3. **UC Extension Course on Dietary Supplements - November 5**
   http://www.unex.berkeley.edu/cat/course905.html

4. FDA Activities Report - Janet McDonald

5. FTC's Activities Report - Jerry Wright

6. Pharmacy Council on Dietary Supplements (PCDS): Status - Fred Mayer

7. Sacramento Update - Sen Speier's office - Prop 37

8. District Attorneys' Report - Cytodyne

9. Berkeley Wellness Letter Report

10. Organization - National scan, with local enforcement

11. Programmatic / CME effort with Amer Pharmacy Association meeting - March, 2006

Thoughts about our next meeting: March 10 or 24, 2006,

Notice to Consumers

Before taking any prescription medicine, talk to your pharmacist; be sure you know:

1. What is the name of the medicine and what does it do?
2. How and when do I take it – and for how long? What if I miss a dose?
3. What are the possible side effects and what should I do if they occur?
4. Will the new medicine work safely with other medicines and herbal supplements I am taking?
5. What foods, drinks or activities should I avoid while taking this medicine?

SENT OUT TO 25,000 PHARMACIES!

Ask your pharmacist if you have additional questions.

At your request, this pharmacy will provide its current retail price of any prescription without obligation. You may request price information in person or by telephone. Ask your pharmacist if a lower cost generic drug is available to fill your prescription. Prescription prices for the same drug vary from pharmacy to pharmacy. One reason for differences in price is differences in services provided.

Exhibit 19

BE AWARE & TAKE CARE

Talk to your Pharmacist!

NOTE!!

California State Board of Pharmacy
(916) 445-5014 • www.pharmacy.ca.gov
400 R Street, Suite 4070, Sacramento, CA 95814

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Attachment D

Board's Response to Comments

Comments from Bob Hansen, PharmD. Vice President Pharmacy Services Asteres Inc. – Staff Response.

1. Support of Regulation.
Asteres urges the Board to approve the regulation change to prevent barriers to using this beneficial new system.

Board's Response.
Thank you for your letter.

Comments from Kevin N. Nicholson, R.Ph, J.D. and Mary Staples, National Association of Chain Drug Stores – Staff Response.

1. Support of Regulation.
For the benefit of consumers and pharmacists, we urge the board to adopt Rule 1713.

Board's Response.
Thank you for your letter.

Comments from Steven Gray, Pharm. D., J.D., Kaiser Permanente – Staff Response

1. The meaning of "Refilled Medications."
"The proposed language limits the use of an "automated delivery device" to "refilled prescription medications" and the term refill is used elsewhere in the proposed regulation. It is our understanding that the purpose of this limitation is to facilitate the requirement for the pharmacy to provide each patient the opportunity for personal consultation what a pharmacist as required by Pharmacy Regulation 1707.2"... "The confusion arises out of the common practice of considering any dispensing medication under a "new" prescription number as a new prescription even though a patient may have been provided the exact same medication, in the exact same strength and dosage form, with the exact same usage for many, many years."

Board Response.
Josh Room, Deputy Attorney General, reviewed Mr. Gray's comment and has provided the board with three options to address Mr. Gray's comments. <u>These options are summarized below and are presented in full following Mr. Gray's letter in Attachment D.</u>

(1) The automated delivery devices can only be used for "refills," as defined by section 4063 and other sections to mean *only* those specifically designated in a prescription. In other words, *only* the subsequent fills of a prescription providing for refills may be put into the device for automated delivery to the patient. If this is the goal, it is probably not necessary to change the regulation, as the meaning should be relatively clear.

(2) The automated delivery devices can be used for any drug that has already previously been dispensed to the patient, assuming there is no change in the drug, dosage, strength, or written instructions. This could be accomplished in any one of several different ways.

(3) Finally, we could settle on some intermediate point, between the more restrictive use of "refill" matching its definition elsewhere, and the more inclusive use of the language from section 1707.2 regarding the duty to consult. For instance, we could arrive at some language allowing for both "refilled" and "renewed" prescription medications to be put in the delivery device, but placing some time limit on the interval between prescriptions or the total number of dispensing transactions consecutively placed in the device as to each drug. Sample language for this alternative could be developed if the board is interested in perusing this option.

2. Use of "Adjacent to the Licensed Pharmacy Counter."
The proposed regulation 1713 uses the phrase "adjacent to the licensed pharmacy counter" in subsection 1713(d)(6)."... In many medical facilities the general medical reception and waiting area is located just outside the licensed pharmacy buy not necessarily "adjacent to the licensed pharmacy counter" because the pharmacy's licensed area may include its own small waiting areas or an area for private consultation...We suggest the following substitute language:

"(6) The devise is located in the facility as near as possible to the pharmacy counter to provide reasonably prompt access to a consulting pharmacist on duty, while, if desired, allowing the devise to be used in the facility after the pharmacy business hours or when no consulting pharmacist is on duty in the pharmacy."

Board Response.
Josh Room, Deputy Attorney General, reviewed Mr. Gray's comment and arrived at the following conclusions: Mr. Gray is concerned that in some Kaiser facilities there may not be a typical pharmacy "counter," and so it is not clear whether those facilities may use the devices, or where they would be placed if they did. More likely than not, these case-by-case determinations could be worked out without requiring a general change in the regulation, as we have tried repeatedly to perfect the language of this subdivision, each iteration has drawn new questions, and we finally settled upon the proposed language as the best compromise. However, it may be possible to both address the issue raised by Mr. Gray and yet maintain the intention of this subpart by just making a simple change of the language to "adjacent to the secure pharmacy area." This would resolve the issue of the absence of a "counter," yet still serve the purpose of requiring that the devices be installed only inside of the licensed premises, and only where they can be secure and within the reasonable control of the pharmacy/pharmacist and where pharmacists can be available (and/or visible) to patients for consultations.

Comments from John Cronin, CPhA – Staff Response

1. Pharmacy Statement.
CPhA believes the board should require pharmacies to provide more specific statements of how the use of these devices will further a high standard of patient safety, promote good patient care and advance pharmacist-patient communication.

Board's Response.
There is no precedence for requiring a pharmacy to write a statement on the benefits of new technology prior to use, such as a statement on the usefulness and benefits from the use of computers in a pharmacy. Requiring a statement from a pharmacy is unlikely to result in any tangible benefit such as improved patient care. Consequently, staff

recommends that the board not incorporate this recommendation into the proposed regulation.

2. Driving Force Behind the Regulation.
CPhA's concern is that a driving force for this regulation appears to be the Board's desire for a system to allow use of these devices that reduces the current administrative burden on the Board and its staff.

Board's Response.
The board advocates the use of technology to improve the quality of pharmacy services to patients when the quality and safety of the service does not decrease. Automated delivery devices have been used in California pharmacies for a year and a half under board waivers and in this time the board has not received any complaints from consumers who have used the machines. Consequently, this regulation is being proposed to allow the use of this technology in pharmacies that choose to use the devices. Under the waiver process the board had little authority to enforce conditions of the waivers. This regulation will allow the board greater enforcement authority over the use of the devices then it had under the waiver process.

3. Technical Changes.
Section 1713(d)(5) reads: "The pharmacy provides a means for each patient to obtain an immediate via telephone or in-person consultation with a pharmacist if requested by the patient.

For clarity, we suggest this be reworded to: "The pharmacy provides a means for each patient to request and obtain an immediate consultation with a pharmacist, either in-person or via telephone."

Board's Response.
Recommend that the board accept this technical change.

Comments from Gary R. Solomon, R.Ph. – Staff Response.

1. Board Approval of Patient Inclusion Criteria.
Change 1713(d)(2) to require a pharmacy submit to the board for approval the pharmacy's policies and procedures criteria for patients to use the device.

Board's Response.
Staff believes that pharmacies with a device and the pharmacist-in-charge that uses the device has a vested interest in ensuring that the policies and procedures required in 1713 will allow for safe and reliable use of the devise. Moving away from issuing waivers for use of the devices and to the adoption of a regulation governing the use of the device will give the board enforcement authority to ensure that the devices are used and operated properly.

2. Board Approval of Device's Method for Identifying Each Patient.
Change 1713(d)(3) to require a pharmacy submit to the board for approval the pharmacy's policies and procedures for the device's means to identify each patient and only release that patient's prescription medications.

Board's Response.
The method each device uses to identify an individual is likely to be determined by the manufacturer of the technology, not the pharmacy that purchases a device. Section 1713(d)(3) is sufficient to ensure that a pharmacy purchase a device that can identify individual patients.

3. Board Approval of Policies and Procedures for Placement of Medications in a Device.
Change 1713(d)(4) to require a pharmacy submit to the board for approval the pharmacy's policies and procedures for a pharmacist to determine which refill medications are not appropriate for dispensing in the device.

Board's Response.
The board will rely on a pharmacist to use his or her best professional judgment for determining which refill medications are appropriate to be placed in the device. Additionally, 1713(e) requires a pharmacy to have written policies and procedures for determining which medications are appropriate for placement in the device and for which patients.

4. Location of the Device and Hours of Operation.
Instead of requiring a device to be located adjacent to a pharmacy, the device should be located no further than 15 to 25 feet from the pharmacy's filling station or pharmacist's counseling station. The device should be operational only during prescription service hours and only when a pharmacist is on duty.

Board's Response.
The placement of a device has been discussed at length. Josh Room, Deputy Attorney General has reviewed various options placement of a device. These options are discussed in Mr. Room's letter in Attachment D.

This regulation has been developed to allow the use of the devices "after hours." Many of the provisions in the regulation are in place specifically to ensure safe use and operation of a device after hours and to guarantee that patients are able to receive the same level of service and consultation that is available when the device is used during regular business hours.

5. Central Fill Responsibility.
If prescription orders come from outside the pharmacy, such as a central fill facility, there should be shared responsibility if the policy and procedure manual requires review of all orders being placed in the device prior to dispensing. If at store level the pharmacist's staff is excluded from this process then the filling entity and pharmacy ownership should bear all responsibility.

Board's Response.
The pharmacist-in-charge (PIC) is ultimately responsible for all medications dispensed at a pharmacy regardless if those medications were filled at a central fill facility or in-store by pharmacy staff. The PIC's responsibility will not change with the addition of an automated dispensing device.

6. Delivery Error Reporting.
Require that any incident involving the device where a complaint, delivery error, or omission be committed to writing within 48 hours of the incident. Require a pharmacy to make a report

to the board within 72 hours if an incident causes hospitalization of the patient or an extreme level of medication intervention.

Board's Response.
Staff does not believe that a device should be held to a higher standard than pharmacy staff. Section 1713 (d)(9) would require any incident involving the device where a complaint, delivery error, or omission has occurred to be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

Comments from Shane Gusman, United Food & Commercial Workers – Staff Response.

1. Patient Care.
We are concerned that unlimited use of *automated delivery systems will result in less interaction between the patient and pharmacist.*

Board's Response.
The board is not aware of any studies that have been conducted on the use of the machines and whether on not the use increase or decreases patients' consult with pharmacists. However, William Homes, ddn Corporation, manufacturer of the Automated Products Machine, stated at the February 1, 2006 board meeting that there is antidotal evidence that suggest that use of the machines has increases patients' requests for consultation with a pharmacist two to one over picking up medications from the pharmacy window, because patients who get their medications quickly feel they can use the time they saved not waiting in line to talk with a pharmacist.

2. Telephone Consult.
Providing patients with a telephone number hardly ensures that there will be somebody else on the other line.

Board's Response.
Section 1713(d)(5) of the proposed regulation requires a pharmacy that uses an automated delivery device to provide a means for each patient to obtain an immediate telephone or in-person consultation with a pharmacist if requested by the patient. This provision is consistent with section 1707.2 Notice to Consumers and Duty to Consult which states "When the patient or agent is not present (including but not limited to a prescription drug that was shipped by mail) a pharmacy shall ensure that the patient receives written notice: (A) of his or her right to request consultation; and (B) a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record." Staff does not believe the standards for ensuring consultation should be higher than those placed on other methods of medication delivery such as mail order.

3. Specific Information Provided to Consumers.
The regulation should specify at a minimum what information should be provided in the patient's written consent. The regulation should also specify what a pharmacy should communicate to patients concerning use of the machines and procedures when the devises malfunction.

Board's Response.
The proposed regulation requires that pharmacies maintain written policies and procedures to ensure that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the automated delivery device and

that participating patients are oriented on use of the automated delivery device, notifying patients when expected prescription medications are not available in the device, and ensuring that patient use of the device does not interfere with delivery of prescription medications. (1713 (e)(3) & (5)) Staff believes that the language of the proposed regulation is sufficient to ensure that patients are informed on the use of the machines as well as their right to consult with a pharmacist.

4. Pharmacist-in-Charge Responsible for Device.
The UFCW is concerned about the potential licensure liability for pharmacists who have these devices where they practice. Pharmacist will not have a say in the placement of the device in their store, yet if the machine malfunctions it will be the pharmacist's license that will be on the line.

Board's Response.
The pharmacist-in-charge (PIC) is responsible for what goes on in the pharmacy. The addition of the delivery devices will not change that. Fortunately for the PIC, pharmacies that have used the device state they have a lower error rate for delivering the wrong prescription than pharmacy staff. In the event that an error occurs or the board believes enforcement action should be taken from improper use or malfunction of a device, the board will look at the facts of the case and determine who is accountable and the appropriate level of enforcement action to take.

5. Make it Clear Pharmacists have Discretion Over Medications Place in Machines.
Make it clear that the pharmacist has complete discretion over what prescriptions are placed in the devices.

Board's Response.
Pharmacist's discretion over medications place in a device is covered in 1713 (d)(4) and 1713 (e)(2), the pharmacy shall have written policies and procedures for determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed.

Comments from Fred S. Mayer, R.Ph., M.P.H. President, PPSI – Staff Response.

1. Kiosk refills for C3s, C4s and C5s in kiosks?

Board's Response.
Schedule IIs will not be permitted in the devices since Schedule II drugs are prohibited from being refill prescriptions. The placement of C3s, C4s and C5s will be left to the discretion of the pharmacist. (1713 (d)(4) and 1713 (e)(2)).

2. Black box warning on Rx's in kiosks?

Board's Response.
Pharmacist's discretion over medications place in a device is covered in 1713 (d)(4) and 1713 (e)(2). If a medication has a black box warning, the board believes that a pharmacist will use his or her best professional judgment to determine whether on not a patient receiving medication with a black box warning should receive consultation on the medication. If consultation is warranted, then a pharmacist will not place the medication in the device.

3. Discretion of pharmacists - How? When? Where? What means?

Board's Response.
Pharmacist's discretion over medications place in a device is covered in 1713 (d)(4) and 1713 (e)(2).

4. A list of what drugs will not be put into kiosks such as insulin, restricted drugs, FDA special warning drugs such as Accutane, etc.

Board's Response.
Pharmacist's discretion over medications place in a device is covered in 1713 (e)(2), the pharmacy shall have written policies and procedures for determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed.

5. A questionnaire or survey to patients and to pharmacists who do not wish to have kiosk prescriptions on their watch.

Board's Response.
Use of the machines by patients is voluntary. Sections 1713(d)(1) and 1713(d)(2) state that "each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so; [additionally] a pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription mediation to that patient."

6. How will consultation issues work for those patients who want further consultation? We understand there will be an 800-telephone number. Who will be answering this phone number? Will someone be available after hours, Sundays, holidays, etc.?

Board's Response.
Section 1713(d)(5) requires "a pharmacy may use an automated delivery device to deliver refilled prescription medications provided that a pharmacy provides a means for each patient to obtain an immediate telephone or in-person consultation with a pharmacist if requested by the patient. If the device is available for patients to access their medications after hours, on Sundays, and holidays then the pharmacy is responsible for ensuring that patients that want to consult with a pharmacist can do so immediately through telephone or in-person consultation.